G. Evaluation Criteria

The application will be reviewed and evaluated according to the following criteria:

1. Understanding the Problem (10 points)

Evidence of the applicant's understanding of the problem and the purpose of the cooperative agreement.

2. Measurable Objectives (20 points)

The consistency of the measurable objectives with the stated purpose of the cooperative agreement and the ability to meet the objectives and timetable within the specified period.

3. Proposed Plan (20 points)

The adequacy of the applicant's plan to carry out the activities proposed. Of particular interest is the potential long-term sustainability of the intervention and the involvement of community organizations.

4. Management and Staffing Plan (35 points)

The extent to which the proposal has described (a) the qualifications and commitment of the applicant in terms of related asthma projects, (b) allocations of time and effort of staff devoted to the project, (c) information on how the applicant will implement and administer the project, (d) the qualifications of the key project staff in terms of asthma related programs and experience.

5. Proposed Evaluation Plan (15 points)

The adequacy of the applicant's plan to monitor progress toward meeting the objectives of the project.

6. Budget (not scored)

The extent to which the budget is reasonable, adequately justified, and consistent with the intended use of the cooperative agreement funds.

H. Other Requirements

Technical Reporting Requirements

Provide CDC with the original plus two copies of:

1. Semi-annual progress reports including the following for each goal or activity involved in the study: (a) comparison of actual accomplishments to the objectives established for the period; (b) the reasons for slippage if objectives were not met; (c) other pertinent information including, when appropriate, analysis and explanation of unexpectedly high costs for performance.

2. Financial status report, no more than 90 days after the end of the budget period, and

3. Final financial status report and performance report no more than 90 days after the end of the project period.

Send all reports to: David Elswick, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, N.E., Room 300, Mailstop E13, Atlanta, GA 30305–2209.

The following additional requirements are applicable to this program. For a complete description of each, see Addendum 1 included in the application kit.

AR98–1—Human Subjects Requirements
AR98–2—Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
AR98–9—Paperwork Reduction Act Requirements
AR98–10—Smoke-Free Workplace Requirements
AR98–11—Healthy People 2000
AR98–12—Lobbying Restrictions
AR98–7—Executive Order 12372
AR98–8—Public Health System Reporting Requirements

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under the Public Health Service Act, section 301(a) [42 U.S.C. 241(a)], as amended. The Catalog of Federal Domestic Assistance number assigned to this project is 98.062.

J. Where To Obtain Additional Information

Please refer to Announcement Number 98062 and contact David Elswick, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, N.E., Room 300, Mailstop E–13, Atlanta, GA 30305–2209, telephone (404) 842–6521, for business management technical assistance.

Programmatic technical assistance may be obtained from James Rifenburg, Air Pollution and Respiratory Health Branch, Division of Environmental Hazards and Health Effects, National Center for Environmental Health, Centers for Disease Control and Prevention (CDC), Mailstop F–39, 4770 Buford Highway, N.E., Atlanta, GA 30341–3724, telephone (770) 488–7322.

Dated: June 15, 1998.

John L. Williams,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98–16325 Filed 6–18–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention (CDC)

[Announcement Number 98068]

Notice of Availability of Funds for Fiscal Year 1998; Grants for Radiation Studies and Research

Introduction

The Centers for Disease Control and Prevention (CDC), announces that applications are being accepted for Grants for Radiation Studies and Research. The efforts funded by these grants will result in models and procedures that will improve systems to track environmental exposures and diseases.

CDC is committed to achieving the health promotion and disease prevention objectives of HEALTHY PEOPLE 2000, a national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the priority areas of Environmental Health. For ordering a copy of HEALTHY PEOPLE 2000, see the section WHERE TO OBTAIN ADDITIONAL INFORMATION.

Authority

This program is authorized under Section 301(a) of the Public Health Service Act [42 U.S.C. Section 241(a)] as amended, and under the Occupational Safety and Health Act [29 U.S.C. Section 669(a)].

Eligible Applicants

Eligible applicants include all non-profit organizations. Thus State and local health departments and other State and local governmental agencies, universities, colleges, research institutions, laboratories, and other public and private organizations, including small, minority and/or woman-owned businesses are eligible for these research grants.

Availability of Funds

Approximately $350,000 is expected to be available in Fiscal Year 1998 to fund approximately two to four awards. It is expected that the average award will be $100,000–$150,000, the range being $60,000 to $200,000 (including both direct and indirect costs). It is expected that the awards will begin on or about September 30, 1998, and are usually made for a 12-month budget period within a project period of up to three years. Funding estimates may vary and are subject to change.

Continuation awards within the project period will be made on the basis of satisfactory progress and the availability of funds.

Use of Funds: Grant funds may not be used to support direct care services.

Background

The Secretary, Department of Health and Human Services (HHS) and the Secretary, Department of Energy (DOE) signed a Memorandum of Understanding (MOU) transferring the authority and resources to manage and conduct energy-related analytic epidemiologic research from DOE to HHS. This includes the authority, resources, and responsibility for the design, implementation, analysis, and scientific interpretation of analytic epidemiologic studies of the following populations: workers at DOE facilities; residents of communities in the vicinity of DOE facilities; other persons potentially exposed to radiation; and persons exposed to potential hazards resulting from non-nuclear energy production and use.

The Secretary, HHS, delegated the responsibility for implementation of the MOU to the Centers for Disease Control and Prevention (CDC). The Director, CDC, designated the National Center for Environmental Health (NCEH) as lead for CDC and for the conduct of environmental studies. The National Institute for Occupational Safety and Health has the responsibility for the conduct of occupational studies.

Purpose

The purposes of this program are:

A. To support radiation research on priority issues in the following categories:

1. A broad-based need for participation in International Validation Studies for Environmental Transport Models.

2. Development of methodologies for using current sampling data as an indicator of past contaminant releases to the environment.

3. Development of Usage Factors for Environmental Dose Calculations.

4. Uncertainty Analysis of Dose Conversion Factors for Radio nuclides.

5. Risk Factors for Thyroid Disease.

6. Development of Ultra sensitive Measurement Techniques for Individual Environmental Radiation Dosimetry.

B. To encourage professionals from a wide spectrum of disciplines such as engineering, medicine, health care, public health, physical sciences, and others, to undertake radiation research programs.

C. To evaluate current and new scientific methodologies and strategies in the areas of radiation research.

Program Requirements

The following are applicant requirements:

A. A director who has specific authority and the responsibility to carry out the project.

B. Demonstrated experience in conducting, evaluating, and publishing radiation, epidemiology, and or dose assessment research.

C. Effective and well-defined working relationships within the performing organization and with outside entities which will ensure implementation of the proposed activities.

D. The ability to disseminate and implement the research findings through organizations (such as public health agencies) or systems, both public and private.

E. An overall match between the applicant's proposed theme and research objectives, and the program priorities as described in the PURPOSE, A. Radiation research.

Eligible applicants may enter into contracts, including consortia agreements (as set forth in the PHS Grants Policy Statement) as necessary to meet the requirements of the program and strengthen the overall application.

Programmatic Interest

The focus of each grant application should reflect priority issues in one or more of the following areas; (1) a broad-based need for participation in International Validation Studies for Environmental Transport Models; (2) development of methodologies for using current sampling data as an indicator of past contaminant releases to the environment; (3) development of Usage Factors for Environmental Dose Calculations; (4) Uncertainty Analysis of Dose Conversion Factors for Radio nuclides; (5) Risk Factors for Thyroid Disease; and (6) Development of Ultra sensitive Measurement Techniques for Individual Environmental Radiation Dosimetry.

International Validation Studies for Environmental Transport Models

The best way to determine the accuracy of any environmental transport model is to compare predictions made by the model with measurements of the same quantity in the environment, a process known as model validation. The environmental transport models potentially useful in dose reconstruction projects must be validated to the extent possible if the results produced by the models are to be scientifically and publicly defensible. A series of recent international projects coordinated by the International Atomic Energy Agency have been attempting to address this issue using environmental radio nuclide data gathered from around the world, especially from nations formerly part of the Soviet Union.

Environmental Indicators of Past Releases

All environmental dose reconstructions will require the extensive use of mathematical models of source term development and environmental transport and dosimetry. These models will be validated against past and present environmental monitoring results. Early environmental monitoring was not as comprehensive or sensitive as today's methods. Therefore, the use of monitoring data for model validation for early years of site operations potentially will be less certain than later years. A number of methods are available for defining long-term trends of environmental contamination. For example, tree ring analyses have been performed to reconstruct historical concentrations of tritium and mercury. Methods developed must provide information on the temporal and geographic patterns of contamination in the environment.

Usage Factors for Environmental Dose Calculations

There are four major factors that determine the dose and risk to people from the inhalation and ingestion of radio nuclides and chemicals released to the environment:

1. the source term (the type and amount of contaminant released to the environment);

2. environmental transport to people (via the atmosphere, hydrosphere, and/or food chains);

3. usage factors (time spent outdoors, rate of inhalation, amount of a particular food product consumed, etc.); and

4. metabolism or the particular radio nuclide or chemical in the body resulting in a particular dose or risk.

What is required for modern dose and risk estimation is a probability distribution for each usage factor.

Uncertainty Analysis of Dose Conversion Factors for Radio Nuclides

All environmental dose reconstructions require the extensive use of Dose Conversion Factors (DCF) that relate intake or exposure to radioactive materials to the endpoint dose. The DCFs in use today have been developed mainly for radiation protection purposes. In as much, these DCFs were derived by the use of conservative values and assumptions, non-stochastic values of DCFs are listed singularly (i.e., with no estimates of

uncertainty). Modern dose and risk estimates require that (1) probability distributions be defined for each of the parameters used to derive the DCF's; (2) each of these distributed parameters be propagated through the model which defines the specific DCF; and (3) the final DCF be presented as a distribution with uncertainties.

Risk Factors for Thyroid Disease

Historical releases of iodine from activities at DOE facilities and during weapons testing have raised questions concerning the risk of thyroid disease associated with radiation exposure. Not only have questions been raised about the risk of thyroid neoplasia, but also about other thyroid diseases that may or may not be related to radiation exposure. Medical monitoring for all thyroid diseases has been proposed for the population around the Hanford nuclear weapons facility potentially exposed to historical releases of radio iodine. A large number of studies have been completed in the last ten years that shed light on the risk factors for thyroid disease and on the association between thyroid disease and radiation.

Development of Ultra Sensitive Measurement Techniques for Individual Environmental Radiation Dosimetry

Much work on environmental dose reconstruction deals with computer modeling using limited environmental monitoring data to ascertain radiation doses to individuals for the purpose of risk assessment and epidemiologic study. This is often due to the fact that the radio nuclides of concern have short effective half lives with respect to the elapsed time from exposure to assessment. In many cases the environmental levels of contamination are significantly below conventional levels of detection for in vivo radiation detection. The purpose of this grant is to develop Ultra sensitive techniques that could be used for assessing environmental exposures to people who are now alive and who may have been exposed to historical releases from DOE weapons facilities. Development of novel techniques or significant improvements on current techniques will be considered.

Application Content

Applications for radiation research should include:

A. The project's focus that justifies the research need and describes the scientific basis for the research, the expected outcome, and the relevance of the findings. The focus should be based on one or more of the priority topic issues.

B. Specific, measurable, and time-framed objectives.

C. A detailed plan describing the methods by which the objectives will be achieved, including their sequence. A comprehensive evaluation plan is an essential component of the application.

D. A description of the grant's principal investigator's role and responsibilities.

E. A description of all project staff regardless of their funding source. It should include their title, qualifications, experience, percentage of time each will devote to the project, as well as that portion of their salary to be paid by the grant.

F. A description of those activities related to, but not supported by the grant.

G. A description of the involvement of other entities that will relate to the proposed project, if applicable. It should include commitments of support and a clear statement of their roles.

H. A detailed first year budget for the grant with future annual projections, if relevant.

I. Applicants must identify the principal priority topic areas upon which their project focuses.

An applicant organization has the option of having specific salary and fringe benefit amounts for individuals omitted from the copies of the application which are made available to outside reviewing groups. To exercise this option, on the original and six copies of the application, the applicant must use asterisks to indicate those individuals for whom salaries and fringe benefits are not shown; the subtotals must still be shown. In addition, the applicant must submit an additional copy of page four of Form PHS–398, completed in full, with the deleted amounts shown. This budget page will be reserved for internal staff use only.

Evaluation Criteria

Applications will be reviewed and evaluated according to the following criteria:

1. The specific aims of the research project, i.e., the broad long term objectives, the intended accomplishment of the specific research proposal, and the hypothesis to be tested; (15 points)

2. The background of the proposal, i.e., the basis for the present proposal, the critical evaluation of existing knowledge, and specific identification of the knowledge gaps which the proposal is intended to fill; (10 points)

3. The significance and originality from a scientific or technical standpoint of the specific aims of the proposed research, including the adequacy of the theoretical and conceptual framework for the research; (20 points)

4. The progress of preliminary studies pertinent to the application; (5 points)

5. The adequacy of the proposed research design, approaches, and methodology to carry out the research, including quality assurance procedures, plan for data management, and a statistical analysis plan; (15 points)

6. The extent to which the evaluation plan will allow for the measurement of progress toward the achievement of the stated objectives; (15 points)

7. Qualifications, adequacy, and appropriateness of personnel to accomplish the proposed activities; (10 points)

8. The degree of commitment and cooperation of other interested parties (as evidenced by letters detailing the nature and extent of the involvement); (5 points)

9. The budget request is clearly explained, adequately justified, reasonable and consistent with the intended use of grant funds; (Not scored) and

10. Adequacy of existing and proposed facilities and resources. (5 points)

Executive Order 12372 Review

Applications are not subject to the review requirements of Executive Order 12372.

Public Health System Reporting Requirement

This program is not subject to the Public Health System Reporting Requirement.

Catalog of Federal Domestic Assistance Number (CFDA)

The Catalog of Federal Domestic Assistance number is 93.283.

Application Submission and Deadlines

Applicants should use Form PHS–398 and adhere to the ERRATA Instruction Sheet for Form PHS–398 contained in the Grant Application Kit. Please submit an original and six copies, on or before August 7,1998 to: David Elswick, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, N.E., Room 300, Atlanta, GA 30305.

Deadlines: Applications shall be considered as meeting a deadline if they are either:

1. Received on or before the deadline date; or

2. Sent on or before the deadline date and received in time for submission to

the review committee. Applicants should request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailings.

Applications which do not meet the criteria in 1. or 2. above are considered late applications and will be returned to the applicant.

Where To Obtain Additional Information

All application procedures and guidelines are contained within the present announcement. Business management technical information may be obtained from David Elswick, Grants Management Specialist, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, N.E., Mailstop E–13, Atlanta, GA 30305, telephone (404) 842–6521.

Programmatic technical assistance may be obtained from Steven Adams, Project Officer, Radiation Studies Branch, Division of Environmental Hazards and Health Effects, National Center for Environmental Health, Centers for Disease Control and Prevention (CDC), 4770 Buford Hwy, N.E., Mailstop F–35, Atlanta, GA 30341–3724, telephone (770) 488–7040.

Potential applicants may obtain a copy of Healthy People 2000 (Full Report, Stock No. 017–001–00474–0) or Healthy People 2000 (Summary Report, Stock No. 017–001–00473–1) through the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402–9325 (Telephone (202) 513–1800).

Dated: June 15, 1998.

John L. Williams,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98–16327 Filed 6–18–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0384]

Knickerbocker Biologicals, Inc.; Revocation of U.S. License No. 458–001

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the establishment license (U.S. License No. 458–001) and the product licenses issued to Knickerbocker Biologicals, Inc., for the manufacture of Whole Blood, Red Blood Cells, Plasma, and Source Leukocytes. Knickerbocker Biologicals, Inc., did not respond to a notice of opportunity for a hearing on a proposal to revoke its licenses.

DATES: The revocation of the establishment license (U.S. License No. 458–001) and the product licenses is effective June 19, 1998.

FOR FURTHER INFORMATION CONTACT: Astrid L. Szeto, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION: FDA is revoking the establishment license (U.S. License No. 458–001) and the product licenses issued to Knickerbocker Biologicals, Inc., doing business as Knickerbocker Blood Bank, 272 Willis Ave., Bronx, NY 10454, for the manufacture of Whole Blood, Red Blood Cells, Plasma, and Source Leukocytes.

An attempted inspection of the facility by FDA revealed that the facility was no longer in operation at the location listed on the license. A certified, returned-receipt letter from FDA dated November 14, 1996, notifying the Responsible Head of the unsuccessful inspection and requesting the status of the firm was returned to the agency as ''undeliverable; address unknown''. A later attempt by FDA to visit three other known addresses of Knickerbocker Biologicals, Inc., New York, NY, verified that the company was no longer in business at these locations. The respective post office for each location was also visited and each verified that no information regarding either a forwarding address or address change was available. Based on the inability of authorized FDA employees to conduct a meaningful inspection of the facility, FDA initiated proceedings for the revocation of the licenses under 21 CFR 601.5(b)(1) and (b)(2). A certified, returned-receipt letter, dated January 24, 1997, to the firm's Responsible Head providing notice of FDA's intent to revoke the licenses and its intent to offer an opportunity for a hearing on the proposed revocation was returned as undeliverable.

Under 21 CFR 12.21(b), FDA published in the **Federal Register** of October 6, 1997 (62 FR 52135), a notice of opportunity for a hearing on a proposal to revoke the licenses of Knickerbocker Biologicals, Inc. In the notice, FDA explained that the proposed license revocation was based on the inability of authorized FDA employees to conduct a meaningful inspection of the facility because it was no longer in operation and noted that documentation in support of the license revocation had been placed on file for public examination with the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. The notice provided the firm 30 days to submit a written request for a hearing and 60 days to submit any data and information justifying a hearing. The notice provided other interested persons with 60 days to submit written comments on the proposed revocation. The firm did not respond within the 30-day time period with a written request for a hearing. The 30-day time period, prescribed in the notice of opportunity for a hearing and in the regulation, may not be extended. No comments were received from any other parties within the 60-day time period.

Accordingly, under 21 CFR 12.38, section 351 of the Public Health Service Act (42 U.S.C. 262), and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Biologics Evaluation and Research (21 CFR 5.68), the establishment license (U.S. License No. 458–001), and the product licenses issued to Knickerbocker Biologicals, Inc., are revoked, effective June 19, 1998.

Dated: May 28, 1998.

Kathryn C. Zoon,

Director, Center for Biologics Evaluation and Research.

[FR Doc. 98–16294 Filed 6–18–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Studies of Adverse Effects of Marketed Drugs; Availability of Grants (Cooperative Agreements); Request for Application

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Center for Drug Evaluation and Research, is announcing $1.4 million for cooperative agreements to study adverse effects of drugs marketed in Canada, the United States and its territories, subject to the availability of Fiscal Year 1999 funds. This amount is consistent with the level