academic, and administrative) for conducting the PFTP? Do they document that their professional personnel involved in the PFTP are qualified and have past experience and achievements related to that proposed? If proposing that fellow's research be conducted at CDC facilities, does the applicant include Letters of Support as described in Application Content section IV.2., above (*i.e.*, that are signed by the appropriate CDC officials and that clearly indicate their commitment to participate as proposed in the application).

3. Operational Plan (30 points): Is the applicant's proposed operational plan clear and detailed and address all Activities listed in Section I? Do they include a detailed time schedule or Gant chart for the first year of the program? Does the applicant clearly indicate specific staff that will be responsible for implementation and operation of the PFTP? Does the applicant's plan meet the purpose and goals of this cooperative agreement program?

4. Measures of Effectiveness (5 points): Does the applicant provide measures of effectiveness as described in the paragraph above such that effective ''outcome'' evaluation can be accomplished?

5. Budget (Not scored): Is the proposed budget reasonable, clearly justified, and consistent with the intended use of grant funds?

V.2. Review and Selection Process

Applications will be reviewed for completeness by the Procurement and Grants Office (PGO) staff, and for responsiveness by the National Center for Infectious Diseases. Incomplete applications and applications that are non-responsive to the eligibility criteria will not advance through the review process. Applicants will be notified that their application did not meet submission requirements.

An objective review panel will evaluate complete and responsive applications according to the criteria listed in the ''V.1. Criteria'' section above.

In addition, the following factors may affect the funding decision:

Preference will be given to competing continuation applications over applications for programs not already receiving support under the PFTP program.

V.3. Anticipated Announcement and Award Dates

Anticipated Award Date: July 1, 2004.

VI. Award Administration Information

VI.1. Award Notices

Successful applicants will receive a Notice of Grant Award (NGA) from the CDC Procurement and Grants Office. The NGA shall be the only binding, authorizing document between the recipient and CDC. The NGA will be signed by an authorized Grants Management Officer, and mailed to the recipient fiscal officer identified in the application.

Unsuccessful applicants will receive notification of the results of the application review by mail.

VI.2. Administrative and National Policy Requirements

45 CFR Part 74 and Part 92

For more information on the Code of Federal Regulations, see the National Archives and Records Administration at the following Internet address: *http://www.access.gpo.gov/nara/cfr/cfr-table-search.html.*

The following additional requirements apply to this project:

- AR–7 Executive Order 12372
- AR–10 Smoke-Free Workplace Requirements
- AR–11 Healthy People 2010
- AR–12 Lobbying Restrictions
- AR–16 Security Clearance Requirement

Additional information on these requirements can be found on the CDC web site at the following Internet address: *http://www.cdc.gov/od/pgo/funding/ARs.htm.*

VI.3. Reporting Requirements

You must provide CDC with an original, plus two hard copies of the following reports:

1. Interim progress report, no less than 90 days before the end of the budget period. The progress report will serve as your non-competing continuation application, and must contain the following elements:

a. Current Budget Period Activities Objectives.

b. Current Budget Period Financial Progress.

c. New Budget Period Program Proposed Activity Objectives.

d. Budget.

e. Additional Requested Information.

f. Measures of Effectiveness.

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

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

These reports must be mailed to the Grants Management or Contract Specialist listed in the ''Agency Contacts'' section of this announcement.

VII. Agency Contacts

For general questions about this announcement, contact: Technical Information Management Section, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770–488–2700.

For program technical assistance, contact: Greg Jones, M.P.A., Public Health Analyst, Office of the Director, National Center for Infectious Diseases, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., Mailstop C12, Atlanta, GA 30333, Telephone: (404) 639–4180, Fax: (404) 639–3106, E-mail: *GJJones@cdc.gov.*

For financial, grants management, or budget assistance, contact: Jeff Napier, Contract Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770–488–2628, E-mail: *jxn1@cdc.gov.*

Dated: May 10, 2004.

William P. Nichols,

Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 04–10948 Filed 5–13–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Request for Applications to Determine the Pharmacokinetics of Clostridium Botulinum Neurotoxins A, B, C, E, and F

Announcement Type: New.

Funding Opportunity Number: 04099.

Catalog of Federal Domestic Assistance Number: 93.283.

Key Dates:

Letter of Intent Deadline: June 1, 2004.

Application Deadline: June 28, 2004.

Executive Summary: The Centers for Disease Control and Prevention (CDC) invites investigator-directed research grant applications that will lead to an understanding of the relationship between oral exposure to Clostridium botulinum neurotoxin, morbidity, and lethality. Research should include, but is not limited to, the establishment and implementation of methods and procedures in non-human primates for determination of the pharmacokinetics of both the di-chain and progenitor forms of C. botulinum neurotoxins A, B, C, E, and F. The information gathered by this study will help guide policy development and most importantly

enable informed treatment recommendations. Applications should define the proposed project goal, interim objectives (development milestone), potential ultimate product, and provide a timeline for milestone and goal attainment. This grant seeks researchers that can collaborate with relevant ongoing small animal studies or that have established small animal models and the ability to transfer these studies to non-human primates. Preference will be given to otherwise equivalent proposals that take measures to minimize suffering and preserve the life of animals utilized in this study to the extent possible. All applicants must comply with CDC guidelines on the care and use of laboratory animals.

I. Funding Opportunity Description

Authority: This program is authorized under the Public Health Service Act Sections 301(a) [42 U.S.C.241(a)], as amended.

Purpose: The purpose of this research grant is to support the development and utilization of a non-human primate model system to gather data on the adsorption, distribution, localization, metabolism and clearance of botulinum neurotoxins. The data obtained from this study will aid the development of methods and procedures to rapidly identify and more effectively treat a human population exposed to botulinum neurotoxin via natural or intentional mechanisms.

The botulinal neurotoxins pose a significant threat to the public as bioterrorist weapons because of their potency, ease of production and transport, and the potential burden that affected individuals would place on the public health care system. These neurotoxins, which are produced by the ubiquitous pathogen Clostridium botulinum and some strains of Clostridium baratii and Clostridium butyricum, are among the most toxic substances known to man. The botulinum neurotoxins (BoNTs) are produced in seven antigenically distinct forms that are identified as types A, B, C, D, E, F, and G. The toxins are naturally found complexed to neuroassociated proteins (progenitor toxin), but can be purified to a fully active di-chain neurotoxin molecule. The BoNTs block the release of the neurotransmitter, acetylcholine, which uncouples the neuromuscular junction and results in paralysis and death if left untreated. Estimates suggest that as little as 1 ng/kg and 3 ng/kg of neurotoxin type A is enough to kill 50 percent of a human population exposed by oral and inhalation routes, respectively.

In the United States, less than 150 cases of laboratory confirmed botulism are reported each year and there are no preventative therapies for the general public at this time as natural cases of botulism are relatively rare. Most cases of botulism traditionally result from exposure to the BoNTs through ingestion of preformed toxin in foods or through secondary means in which a toxin producing organism is introduced and becomes established in the body. Inhalational botulism is not a common form of exposure. Most of the information on botulinum intoxication and treatment in humans is derived from cases of naturally occurring foodborne botulism. Neurological signs of botulism in humans include: symmetric, descending flaccid paralysis with bulbar palsies, ptosis, diplopia, blurred vision, enlarged pupils, dysarthria, dysphonia, and dysphagia. The lag time between exposure and rapidity of symptom onset is difficult to establish in naturally occurring foodborne cases as it is dependent on the rate and amount of toxin ingested by each affected individual among other variables. At this time, clinical presentation consistent with botulism, which may occur 12–72 hours after toxin ingestion, is the only basis for implementation of antitoxin therapy, which will stop the progression of neuronal damage but not reverse it. Although clinical specimens such as aspirates, serum and stool can be analyzed for the presence of BoNT, the absence of toxin in such specimens does not rule out intoxication. Thus, although it is crucial that BoNT exposed individuals are identified and appropriately treated in a timely manner, insufficient data are available to establish a defined time line between exposure to botulinum toxin, adsorption by mucosal tissues, toxin stability in vivo, toxin serum levels over time, and clearance.

Currently, the treatment of botulism patients requires extensive supportive care and passive immunization with equine antitoxin. Data from outbreaks resulting from ingestion of naturally contaminated foods suggest that up to 95 percent of exposed individuals require hospitalization and up to 62 percent require long-term ventilation. This suggests that with our current capabilities, a large outbreak would place an enormous strain on the existing health care infrastructure, possibly limiting treatment capacity. Although modern antitoxin therapy treatments are highly effective in reducing mortality in humans, existing supplies need to be used in an effective and timely manner.

The determination of the pharmacokinetics of the BoNTs resulting from oral exposure will provide critical information that will aid early identification of exposed individuals and enable the development of informed guidelines that will maximize effective delivery of therapeutic antitoxin in a large scale outbreak.

This program addresses the ''Healthy People 2010'' focus area of Immunization and Infectious Disease.

Measurable outcomes of the program will be in alignment with the following performance goal for the National Center for Infectious Diseases (NCID): Protect Americans from infectious diseases.

Research Objectives: Develop and utilize a non-human primate model system to determine the pharmacokinetics of both di-chain and progenitor forms of C. botulinum neurotoxins A, B, C, E, and F resulting from low to high level toxin exposure. The product of this research should establish a timeline of events and a relationship among the following: C. botulinum toxin exposure level, neurotoxin type (A, B, C, E, and F), toxin form (di-chain and progenitor toxin), rate of toxin adsorption into serum, distribution and quantity of toxin in body fluids and products (serum, and stool), toxin stability/duration of action, time of botulism symptom onset (as related to time of exposure, and toxin serum levels), biotransformation of toxin in body fluids/products (*i.e.* presence of progenitor, di-chain, or another form of the toxin), rate of toxin clearance, variability in exposed population, and recovery.

Activities: Awardee activities for this program but are not limited to the following:

- Establish a relevant small animal model (examples include guinea pigs or mice) to conduct pharmacokinetic studies on botulinum toxins that can be transferred to non-human primate studies. Alternatively, it is acceptable to establish collaboration with researcher(s) conducting ongoing small animal studies and to propose how those studies would be transferred to non-human primates.
- Develop protocols and procedures for testing, maintenance, and recovery of non-human primates.
- Describe a timeframe for development of a proof-of-concept small animal model, establishment of a non-human primate model, attainment of necessary materials to perform the study, collection and analysis of clinical specimens, and completion of the study.

• Develop and implement protocols to address the research objectives in a non-human primate model system, including but not limited to methods for oral toxin exposure, collection and testing of appropriate tissues and or body fluids/products, evaluation of botulism symptom onset, and evaluation of intra-study variation among test subjects.

II. Award Information

Type of Award: Grant.
Award Mechanism: R01.
Fiscal Year Funds: 2004.
Approximate Total Funding: $2,000,000.00.
Approximate Number of Awards: 1–2.
Approximate Average Award: $900,000.00.
Floor of Award Range: None.
Ceiling of Award Range: None.
Anticipated Award Date: September 1, 2004.
Budget Period Length: 12 months.
Project Period Length: 3 years.

Throughout the project period, CDC's commitment to continuation of awards will be conditioned on the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports), and the determination that continued funding is in the best interest of the Federal Government.

III. Eligibility Information

III.1. Eligible Applicants

Applications may be submitted by public and private organizations and by governments and their agencies, such as:

- Public nonprofit organizations.
- Private organizations.
- Universities.
- Colleges.
- Research institutions.
- Hospitals.
- Community-based organizations.
- Faith-based organizations.
- Federally recognized Indian tribal governments.
- Indian tribal organizations.
- State and local governments or their Bona Fide Agents (this includes the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Marianna Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau).
- Political subdivisions of States (in consultation with States).

A Bona Fide Agent is an agency/organization identified by the state as eligible to submit an application under the state eligibility in lieu of a state application. If you are applying as a bona fide agent of a state or local government, you must provide a letter from the state or local government as documentation of your status. Place this documentation behind the first page of your application form.

III.2. Cost Sharing or Matching

Matching funds are not required for this program.

III.3. Other

If your application is incomplete or non-responsive to the requirements listed in this section, it will not be entered into the review process. You will be notified that your application did not meet submission requirements.

Individuals Eligible to Become Principal Investigators: Any individual with the skills, knowledge, and resources necessary to carry out the proposed research is invited to work with their institution to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for CDC programs.

Note: Title 2 of the United States Code section 1611 states that an organization described in section 501(c)(4) of the Internal Revenue Code that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, or loan.

IV. Application and Submission Information

IV.1. Address to Request Application Package

To apply for this funding opportunity, use application form PHS 398 (OMB number 0925–0001 rev. 5/2001). Forms and instructions are available in an interactive format on the CDC Web site, at the following Internet address: *http://www.cdc.gov/od/pgo/forminfo.htm.* Forms and instructions are also available in an interactive format on the National Institutes of Health (NIH) Web site at the following Internet address: *http://grants.nih.gov/grants/funding/phs398/phs398.html.*

If you do not have access to the Internet, or if you have difficulty accessing the forms on-line, you may contact the CDC Procurement and Grants Office Technical Information Management Section (PGO–TIM) staff at: 770–488–2700. Application forms can be mailed to you.

IV.2. Content and Form of Application Submission

Letter of Intent (LOI): Your LOI must be written in the following format:

- Maximum number of pages: 3.
- Font size: 12-point unreduced.
- Single spaced.
- Paper size: 8.5 by 11 inches.
- Page margin size: One inch.
- Printed only on one side of page.
- Written in plain language, avoid jargon.

Your LOI must contain the following information:

- Descriptive title of the proposed research.
- Name, address, E-mail address, and telephone number of the Principal Investigator.
- Names of other key personnel.
- Participating institutions.
- Number and title of this Program Announcement.

Application: Follow the PHS 398 application instructions for content and formatting of your application. For further assistance with the PHS 398 application form, contact PGO–TIM staff at 770–488–2700, or contact GrantsInfo, Telephone (301) 435–0714, E-mail: GrantsInfo@nih.gov.

Your research plan should address activities to be conducted over the entire project period.

You are required to have a Dun and Bradstreet Data Universal Numbering System (DUNS) number to apply for a grant or cooperative agreement from the Federal government. Your DUNS number must be entered on line 11 of the face page of the PHS 398 application form. The DUNS number is a nine-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, access *http://www.dunandbradstreet.com* or call 1–866–705–5711. For more information, *see* the CDC Web site at: *http://www.cdc.gov/od/pgo/funding/pubcommt.htm.*

This PA uses just-in-time concepts. It also uses the modular budgeting as well as non-modular budgeting formats. *See: http://grants.nih.gov/grants/funding/modular/modular.htm* for additional guidance on modular budgets. Specifically, if you are submitting an application with direct costs in each year of $250,000 or less, use the modular budget format. Otherwise, follow the instructions for non-modular budget research grant applications.

Additional requirements that may require you to submit additional documentation with your application are listed in section ''VI.2. Administrative and National Policy Requirements.''

IV.3. Submission Dates and Times

LOI Deadline Date: June 1, 2004. CDC requests that you send a LOI if you

intend to apply for this program. Although the LOI is not required, not binding, and does not enter into the review of your subsequent application, the LOI will be used to gauge the level of interest in this program, and to allow CDC to plan the application review.

Application Deadline Date: June 28, 2004.

Explanation of Deadlines: Applications must be received in the CDC Procurement and Grants Office by 4 p.m. eastern time on the deadline date. If you send your application by the United States Postal Service or commercial delivery service, you must ensure that the carrier will be able to guarantee delivery of the application by the closing date and time. If CDC receives your application after closing due to: (1) carrier error, when the carrier accepted the package with a guarantee for delivery by the closing date and time, or (2) significant weather delays or natural disasters, you will be given the opportunity to submit documentation of the carriers guarantee. If the documentation verifies a carrier problem, CDC will consider the application as having been received by the deadline.

This announcement is the definitive guide on application submission address and deadline. It supersedes information provided in the application instructions. If your application does not meet the deadline above, it will not be eligible for review, and will be discarded. You will be notified that your application did not meet the submission requirements.

CDC will not notify you upon receipt of your application. If you have a question about the receipt of your application, first contact your courier. If you still have a question, contact the PGO–TIM staff at: 770–488–2700. Before calling, please wait two to three days after the application deadline. This will allow time for applications to be processed and logged.

IV.4. Intergovernmental Review of Applications

Your application is subject to Intergovernmental Review of Federal Programs, as governed by Executive Order (EO) 12372. This order sets up a system for state and local governmental review of proposed federal assistance applications. You should contact your state single point of contact (SPOC) as early as possible to alert the SPOC to prospective applications, and to receive instructions on your state's process. Click on the following link to get the current SPOC list: *http://www.whitehouse.gov/omb/grants/spoc.html.*

IV.5. Funding restrictions

Restrictions, which must be taken into account while writing your budget, are as follows:

- None.

If you are requesting indirect costs in your budget, you must include a copy of your indirect cost rate agreement. If your indirect cost rate is a provisional rate, the agreement should be less than 12 months of age.

Awards will not allow reimbursement of pre-award costs.

IV.6. Other Submission Requirements

LOI Submission Address: Submit your LOI by express mail, delivery service, fax, or E-mail to: Barbara Stewart, Centers for Disease Control and Prevention, National Center for Infectious Diseases, 1600 Clifton Road, NE., Mail Stop C–19, Atlanta, GA 30333, Phone: 404–639–0044, Fax: 404–639–2469, E-mail Address: *bsg2@cdc.gov.*

Application Submission Address: Submit the original and five hard copies of your application by mail or express delivery service to: Technical Information Management-PA# 04099, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341.

Applications may not be submitted electronically at this time.

V. Application Review Information

V.1. Criteria

You are required to provide measures of effectiveness that will demonstrate the accomplishment of the various identified objectives of the grant. Measures of effectiveness must relate to the performance goals stated in the ''Purpose'' section of this announcement. Measures must be objective and quantitative, and must measure the intended outcome. These measures of effectiveness must be submitted with the application and will be an element of evaluation.

The goals of CDC-supported research are to advance the understanding of biological systems, improve the control and prevention of disease and injury, and enhance health. In the written comments, reviewers will be asked to evaluate the application in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals.

The scientific review group will address and consider each of the following criteria in assigning the application's overall score, weighting them as appropriate for each application. The application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a high priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative, but is essential to move a field forward.

The criteria are as follows:

Significance: Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field? Will this study make significant contributions to the existing knowledge base regarding effective antitoxin treatment of botulinum toxin exposed individuals?

Approach: Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics? Has the applicant outlined a reasonable plan for attaining the objectives of this project within the indicated time frame? Are standardized operating procedures and documentation practices described?

Innovation: Does the project employ novel concepts, approaches or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

Investigator: Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)?

Environment: Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support? Is the entity or facility conducting the experiments approved to work with botulinum toxin by the Select Agent Program?

Additional Review Criteria: In addition to the above criteria, the following items will be considered in the determination of scientific merit and priority score:

Study Animal Model(s): Are the animal models described appropriate for attainment of study objectives? Has the applicant described a reasonable timeline and approach for development and implementation of a non-human primate model system? Has the applicant described an approach that will enable satisfactory attainment of the study objectives? Are adequate treatment/therapy methods described

for non-human primates used in this study?

Laboratory Analysis and Clinical Evaluation: Has the applicant described satisfactory methods for collection of clinical specimens? Is a method described for analysis of clinical specimens and is this method adequately sensitive to detect relevant levels of toxin? Does the applicant recognize potential problems regarding sensitive detection of toxin in clinical specimens and considered alternative strategies? Has the applicant provided background and experience for the entity conducting laboratory testing, if applicable? Has the applicant described a reasonable method for evaluation of botulism symptom presentation in small animals and non-human primates?

Study Timeline and Protocol: Has the applicant described a reasonable timeframe for completion of the proof-of-concept small animal study, initiation and completion of the non-human primate study, collection and analysis of clinical specimens, reporting, and successful completion of the program?

Protection of Human Subjects from Research Risks: Does the application adequately address the requirements of Title 45 CFR Part 46 for the protection of human subjects? This will not be scored; however, an application can be disapproved if the research risks are sufficiently serious and protection against risks is so inadequate as to make the entire application unacceptable.

Inclusion of Women and Minorities in Research: Does the application adequately address the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research? This includes: (1) The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation; (2) The proposed justification when representation is limited or absent; (3) A statement as to whether the design of the study is adequate to measure differences when warranted; and (4) A statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits.

Care and Use of Vertebrate Animals in Research: If vertebrate animals are to be used in the project, the five items described under Section f of the PHS 398 research grant application instructions will be assessed.

Budget: The reasonableness of the proposed budget and the requested period of support in relation to the proposed research.

V.2. Review and Selection Process

Applications will be reviewed for completeness by the Procurement and Grants Office (PGO) and for responsiveness by NCID. Incomplete applications and applications that are non-responsive to the eligibility criteria will not advance through the review process. Applicants will be notified that their application did not meet submission requirements.

Applications that are complete and responsive to the PA will be evaluated for scientific and technical merit by an appropriate peer review group or charter study section convened by NCID in accordance with the review criteria listed above. As part of the initial merit review, all applications may:

- Undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of the applications under review, will be discussed and assigned a priority score.
- Receive a written critique.
- Receive a second level review by CDC senior staff.

Award Criteria: Criteria that will be used to make award decisions include:

- Scientific merit (as determined by peer review).
- Ability of proposal to attain research objectives.
- Availability of funds.
- Programmatic priorities.

V.3. Anticipated Announcement and Award Dates

Anticipated Award Date: September 1, 2004.

VI. Award Administration Information

VI.1. Award Notices

Successful applicants will receive a Notice of Grant Award (NGA) from the CDC Procurement and Grants Office. The NGA shall be the only binding, authorizing document between the recipient and CDC. The NGA will be signed by an authorized Grants Management Officer, and mailed to the recipient fiscal officer identified in the application.

Unsuccessful applicants will receive notification of the results of the application review by mail.

VI.2. Administrative and National Policy Requirements

45 CFR Parts 74 and 92

For more information on the Code of Federal Regulations, see the National Archives and Records Administration at the following Internet address: *http://www.access.gpo.gov/nara/cfr/cfr-table-search.html.*

The following additional requirements apply to this project:

- AR–1 Human Subjects Requirements.
- AR–2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research.
- AR–3 Animal Subjects Requirements.
- AR–7 Executive Order 12372.
- AR–10 Smoke-Free Workplace Requirements.
- AR–11 Healthy People 2010.
- AR–12 Lobbying Restrictions.
- AR–15 Proof of Non-Profit Status.
- AR–22 Research Integrity.
- AR–23 States and Faith-Based Organizations.
- AR–25 Release and Sharing of Data.

Additional information on these requirements can be found on the CDC Web site at the following Internet address: *http://www.cdc.gov/od/pgo/funding/ARs.htm.*

VI.3. Reporting

You must provide CDC with an original, plus two hard copies of the following reports:

1. Interim progress report, (use form PHS 2590, OMB Number 0925–0001, rev. 5/2001 as posted on the CDC Web site) no less than 90 days before the end of the budget period. The progress report will serve as your non-competing continuation application, and must contain the following elements:

a. Current Budget Period Activities Objectives.

b. Current Budget Period Financial Progress.

c. New Budget Period Program Proposed Activity Objectives.

d. Budget.

e. Additional Requested Information.

f. Measures of Effectiveness.

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

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

These reports must be mailed to the Grants Management Specialist listed in the ''Agency Contacts'' section of this announcement.

VII. Agency Contacts

For general questions about this announcement, contact: Technical Information Management Section, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770–488–2700.

For scientific/research issues, contact: Dr. Mary Lerchen, Acting Director, Office of Extramural Research, CDC, National Center for Infectious Diseases,

1600 Clifton Road, NE., Mailstop: C–19, Atlanta, GA 30333, Telephone: 404–639–0043, E-mail: *mll0@cdc.gov*.

For questions about peer review, contact: Barbara Stewart, Public Health Analyst, CDC, National Center for Infectious Diseases, 1600 Clifton Road, NE., Mailstop: C–19, Atlanta, GA 30333, Telephone: 404–639–0044, E-mail: *bsg2@cdc.gov*.

For financial, grants management, or budget assistance, contact: Jeff Napier, Contract Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770–488–2628, E-mail: *JNapier@cdc.gov*.

VIII. Other Information

None.

Dated: May 10, 2004.

Bill Nichols,

Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 04–10947 Filed 5–13–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–R–214, CMS–179, CMS–367, 367–A, 367–C and CMS–417]

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

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) (formerly known as the Health Care Financing Administration (HCFA)), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Independent Diagnostic Testing Facility and Supporting Regulations contained in 42 CFR 410.33; *Form No.:* CMS–R–214 (OMB# 0938–0721); *Use:* The information collection requirements associated with an Independent Diagnostic Testing Facilities involve documentation of proficiency of medical personnel and of resources; *Frequency:* Annually; *Affected Public:* Business or other for-profit, Federal Government and State, local and tribal government; *Number of Respondents:* 500; *Total Annual Responses:* 500; *Total Annual Hours:* 42.

2. *Type of Information Request:* Extension of a currently approved collection; *Title of Information Collection:* Transmittal and Notice of Approval of State Plan Material and Supporting Regulations in 42 CFR 430.10–430.20 and 440.167; *Form Number:* CMS–179 (OMB approval #: 0938–0193); *Use:* Form CMS–179 is used by State agencies to transmit State plan material to CMS for approval prior to amending their State plans; *Frequency:* On occasion; *Affected Public:* State, local or tribal gov't; *Number of Respondents:* 56; *Total Annual Responses:* 56; *Total Annual Hours Requested:* 560.

3. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicaid Drug Rebate Program—Manufacturers; *Form No.:* 0938–0578 (CMS–367, 367a, and 367c); *Use:* Section 1927 requires drug manufacturers to enter into and have in effect a rebate agreement with the Federal Government for States to receive funding for drugs dispensed to Medicaid recipients; *Frequency:* Quarterly; *Affected Public:* Business or other for-profit; *Number of Respondents:* 570; *Total Annual Responses:* 2,280; *Total Annual Hours:* 54,780.

4. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Hospice Request for Certification in the Medicare Program; *Form No.:* CMS–417 (OMB# 0938–0313); *Use:* The Hospice Request for Certification Form is used for hospice identification, screening, and to initiate the certification process. The information captured on this form is entered into a data base which assists CMS in determining whether providers have sufficient personnel to participate in the Medicare program; *Frequency:* Annually; *Affected Public:* Business or other for-profit, Not-for-profit institutions, Federal Government, and State, local or tribal government; *Number of Respondents:* 2,286; *Total Annual Responses:* 2,286; *Total Annual Hours:* 572.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web Site address at *http://cms.hhs.gov/regulations/pra/default.asp,* or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@hcfa.gov,* or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Brenda Aguilar, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: May 6, 2004.

John P. Burke, III,

Paperwork Reduction Act Team Leader, CMS Reports Clearance Officer, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10110, CMS–102–105, CMS–R–216, CMS–10047 and CMS–18F5]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) (formerly known as the Health Care Financing Administration (HCFA)), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions;