V.2. Review and Selection Process

Applications will be reviewed for completeness by the Procurement and Grants Office (PGO), and for responsiveness by OPHR. 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 announcement will be evaluated for scientific and technical merit by an appropriate peer review group or charter study section, a Special Emphasis Panel (SEP), convened by the OPHR in accordance with the review criteria listed above. As part of the initial merit review, all applications will:

- Undergo a peer review by a SEP. The SEP will be selected from the NIH pool of scientists or recommendations from the NIP to serve as reviewers on SEPs. Applications will be ranked for the secondary review according to scores submitted by the SEP. Only those applications deemed to have the highest scientific merit by the review group, generally the top half of the applications under review, will be discussed and assigned a priority score.
- Receive a written critique.
- Receive a second programmatic level review by the Office of Science, NIP.

Award Criteria: Criteria that will be used to make award decisions during the programmatic review include:

- Scientific merit (as determined by peer review).
- Availability of funds.
- Programmatic priorities.

V.3. Anticipated Announcement and Award Dates:

August 31, 2005.

VI. Award Administration Information

VI.1. Award Notices

Successful applicants will receive a Notice of Award (NoA) from the CDC Procurement and Grants Office. The NoA shall be the only binding, authorizing document between the recipient and CDC. The NoA 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–1 Human Subjects Requirements.
- AR–2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research.
- AR–6 Patient Care.
- AR–7 Executive Order 12372.
- AR–8 Public Health System Reporting Requirements.
- AR–10 Smoke-Free Workplace Requirements.
- AR–11 Healthy People 2010.
- AR–12 Lobbying Restrictions.
- AR–14 Accounting System Requirements.
- AR–15 Proof of Non-Profit Status.
- AR–22 Research Integrity.
- AR–23 States and Faith-Based Organizations.
- AR–24 Health Insurance Portability and Accountability Act Requirements.
- 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. 9/2004 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 additional elements:

a. Progress Toward Measures of Effectiveness.

b. Additional Information Requested by Program.

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 Specialist listed in the ''Agency Contacts'' section of this announcement.

VII. Agency Contacts

We encourage inquiries concerning this announcement. For general questions, 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: Susan Chu, PhD, MSPH, Extramural Program Official, Centers for Disease Control and Prevention, MS E–05, 1600 Clifton Road, Atlanta, GA 30333. Telephone: 404–639–8727. E-mail: *SChu@cdc.gov.*

For questions about peer review, contact: Mary Lerchen, DrPH, Scientific Review Administrator, CDC/Office of Public Health Research, One West Court Square, Suite 7000, MS D–72. Telephone: 404–371–5277. Fax: 404–371–5215. E-mail: *MLerchen@cdc.gov.*

For financial, grants management, or budget assistance, contact: Ann Cole, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341. Telephone: 770–488–2686. E-mail: *ZLR5@cdc.gov.*

VIII. Other Information

This and other CDC funding opportunity announcements can be found on the CDC Web site, Internet address: *http://www.cdc.gov.* Click on ''Funding'' then ''Grants and Cooperative Agreements.''

Dated: May 4, 2005.

William P. Nichols,

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

[FR Doc. 05–9274 Filed 5–9–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Expanding the Utilization of Pro-Active Pharmacist Pneumococcal Vaccination Programs

Announcement Type: New.

Funding Opportunity Number: RFA IP05–092.

Catalog of Federal Domestic Assistance Number: 93.185.

Letter of Intent Deadline: June 9, 2005.

Application Deadline: June 24, 2005.

I. Funding Opportunity Description

Authority: Section 311 [42 U.S.C. 243] and 317(k)(1) [42 U.S.C. 247b(k)(1)] of the Public Health Service Act, as amended.

Background

Pneumococcal vaccination rates are less than 50 percent among persons 18–64 with conditions that are indications for vaccination, with particularly low

rates among persons 18–49. In the clinical setting, the challenge of targeting patients based on medical conditions in contrast to targeting based on age is thought to contribute to these low vaccination rates. Pharmacists are in an excellent position to both counsel high-risk patients about pneumococcal vaccination, as well as to offer them pneumococcal vaccinations since vaccination by pharmacists is currently authorized in 43 states. A high proportion of persons that take prescription medication have frequent contacts with pharmacists. Pharmacists, in turn, can identify persons with indications for pneumococcal vaccination. Patients taking medication for chronic cardiovascular disease (*e.g.* congestive heart failure, cardiomyopathies), chronic pulmonary disease (COPD, emphysema), and chronic liver disease are candidates for pneumococcal vaccinations.

It has been shown that customers respond well to pharmacist recommendation and it has also been shown that pharmacist vaccination is effective in increasing vaccination rates among their clients (1–3). Methods used have included patient reminders (either in the form of a sticker on a medication or a mailed reminder) or proactive offering of vaccination when prescriptions are filled.

Citations

1. Grabenstein JD *et al.* ''Effect of vaccination by community pharmacists among adult prescription recipients''. ''Medical Care 2001''; 39:340–348.

2. Grabenstein JD. *et al.* ''Community pharmacists as immunization advocates: a clinical pharmacoepidemiologic experiment''. ''Internat J Pharm Pract. 1993''; 2:5–10.

3. Ernst ME *et al.* ''Implementation of a community pharmacy-based influenza vaccination program''. ''J Am Pharm Assoc 1997''; 37:570–80.

Purpose

The purpose of this program is to examine the feasibility of expanding the utilization of pro-active pharmacist influenza vaccination programs and examine the impact of such programs on pneumococcal vaccination rates among pharmacy clients.

This program addresses the ''Healthy People 2010'' focus area(s) of Immunization and Infectious Diseases.

Measurable outcomes of the program will be in alignment with the performance goal for the Centers for Disease Control and Prevention's (CDC) National Immunization Program (NIP) to reduce the number of indigenous vaccine-preventable diseases.

Research Objectives

- Identify pharmacies without pro-active pharmacist vaccination programs.
- Establish new pro-active pharmacist vaccination programs.
- Determine the adoption rate of pharmacist vaccination and impact on pneumococcal vaccination rates among pharmacy clients.
- Determine resources needed to implement pro-active pharmacist vaccination programs.

Activities

Awardee activities for this program are as follows:

- Define a study universe of pharmacies that will be targeted for implementation of pro-active offering of vaccine (ways in which the universe is defined include, but are not limited to, a pharmacy chain or all pharmacies in a community). This sample should include pharmacies that serve clients with a range of sociodemographic characteristics and should include at least 30 pharmacies.
- Determine the conditions and respective indicator medications that will be targeted based on the relative prevalence of indications for pneumococcal vaccination in customer population in age group. At least three conditions should be included.
- Promote the implementation of pro-active offering of pneumococcal vaccination, providing technical assistance as needed. To promote continuity of care, pharmacies should plan to inform primary care providers when clients have received pneumococcal vaccine by sending them information for the patient's records (*e.g.* by mail or fax).
- Although the primary interest is pneumococcal vaccination in persons 18–64 with high risk conditions, interventions can be expanded to include persons 65 and older (targeted based on age rather than indicator medications) and to include influenza vaccination. Implementation of pneumococcal vaccination outside of the influenza vaccination season may be optimal given added work-load related to influenza vaccination activities.
- Develop an evaluation protocol that will include determining baseline pharmacy vaccination practices, determining rate of adoption (the number of pharmacies approached, the number interested, the number that implemented), determining the impact of the intervention among those not previously vaccinated (number/percent of high-risk clients assessed and vaccinated), determining barriers to adoption and to effective implementation, and pharmacist and customer attitudes.
- Quantifying resources needed to achieve program implementation.
- Identify key staff available to develop project.
- Collaboratively disseminate research findings in peer-reviewed publications and for use in determining national policy.

In a cooperative agreement, CDC staff is substantially involved in the program activities, above and beyond routine grant monitoring.

CDC Activities for this program are as follows:

- Provide CDC investigator(s) to monitor the cooperative agreement as project officer(s).
- Participate as active project team members in the development, implementation and conduct of the research project and as coauthors of all scientific publications that result from the project.
- Provide technical assistance on the selection and evaluation of data collection and data collection instruments.
- Assist in the development of research protocols for Institutional Review Boards (IRB) review. The CDC IRB will review and approve the project protocol initially and on at least an annual basis until the research project is completed.
- Contribute subject matter expertise in the areas of epidemiologic methods and statistical analysis, and survey research consultation.
- Participate in the analysis and dissemination of information, data and findings from the project, facilitating dissemination of results.
- Serve as liaisons between the recipients of the project award and other administrative units within the CDC.
- Facilitate an annual meeting between awardee and CDC to coordinate planned efforts and review progress.

II. Award Information

Type of Award: Cooperative Agreement.

CDC involvement in this program is listed in the Activities Section above.

Mechanism of Support: U01.

Fiscal Year Funds: 2005.

Approximate Total Funding: $150,000 (Includes direct and indirect costs. This amount is an estimate, and is subject to availability of funds.)

Approximate Number of Awards: One.

Approximate Average Award: $150,000 (Includes direct and indirect costs. This amount is for the first 12-month budget period.)

Floor of Award Range: None.

Ceiling of Award Range: $150,000 (Includes direct and indirect costs. This ceiling is for the first 12-month budget period.)

Anticipated Award Date: August 31, 2005.

Budget Period Length: 12 months.

Project Period Length: 2 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 are limited to public and private nonprofit organizations and by governments and their agencies, such as: (For profit organizations are not eligible under Section 317(k)(1) [42 U.S.C. 247b(k)(1) of the Public Health Service Act, as amended.)

- Public nonprofit organizations
- Private nonprofit organizations
- Small, minority, women-owned businesses
- Universities
- Colleges
- Research institutions
- Hospitals
- Community-based organizations
- Faith-based organizations
- Federally recognized Indian tribal governments
- Indian tribes
- 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 you request a funding amount greater than the ceiling of the award range, your application will be considered non-responsive, and will not be entered into the review process. You will be notified that your application did not meet the submission requirements.

Special Requirements

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.

- Late applications will be considered non-responsive. See section ''IV.3. Submission Dates and Times'' for more information on deadlines.
- **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.

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.

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. 9/2004). 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: 2
- Font size: 12-point unreduced
- Double 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, telephone number, and FAX number of the Principal Investigator
- Names of other key personnel
- Participating institutions
- Number and title of this 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/pubcommt1.htm.*

This announcement uses the non-modular budgeting format.

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 9, 2005.

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 24, 2005.

Explanation of Deadlines: LOIs must be received in the CDC Office of Public Health Research (OPHR) and applications must be received in the CDC Procurement and Grants Office by 4 p.m. Eastern Time on the deadline date. If you submit your LOI or application by the United States Postal Service or commercial delivery service, you must ensure that the carrier will be able to guarantee delivery by the closing date and time. If CDC receives your submission 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 submission as having been received by the deadline.

This announcement is the definitive guide on LOI and application content, 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 you did not meet the submission requirements.

CDC will not notify you upon receipt of your submission. If you have a question about the receipt of your LOI or application, first contact your courier. If you still have a question concerning your LOI, contact the OPHR staff at 404–371–5277. If you still have a question concerning your application, contact the PGO-TIM staff at: 770–488–2700. Before calling, please wait two to three days after the submission deadline. This will allow time for submissions 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:

- Funds relating to the conduct of research will not be released until the appropriate assurances and IRB approvals are in place.
- Reimbursement of pre-award costs is not allowed.

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.

IV.6. Other Submission Requirements

LOI Submission Address: Submit your LOI by express mail, delivery service, fax, or E-mail to: Mary Lerchen, DrPH, Scientific Review Administrator, CDC/Office of Public Health Research, One West Court Square, Suite 7000, MS D–72, Telephone: 404–371–5277, Fax: 404–371–5215, E-mail: *MLerchen@cdc.gov*.

Application Submission Address: Submit the original and one hard copy of your application by mail or express delivery service to: Technical Information Management Section'' RFA IP05–092, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341.

At the time of submission, four additional copies of the application, and all appendices must be sent to: Mary Lerchen, DrPH, Scientific Review Administrator, CDC/Office of Public Health Research, One West Court Square, Suite 7000, MS D–72, Telephone: 404–371–5277, Fax: 404–371–5215, E-mail: *MLerchen@cdc.gov*.

Applications may not be submitted electronically at this time.

V. Application Review Information

V.1. Criteria

Applicants are required to provide measures of effectiveness that will demonstrate the accomplishment of the various identified objectives of the cooperative agreement. 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 equally 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 review 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?

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?

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? Are letters of support included, if applicable?

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

Preference will be given to applicants with a demonstrated relationship with pharmacies as evidenced by letters of support and/or previous demonstrated successful collaboration. Place this

documentation behind the first page of your application form.

Protection of Human Subjects from Research Risks: Does the application adequately address the requirements of Title 45 Part 46 for the protection of human subjects? The involvement of human subjects and protections from research risk relating to their participation in the proposed research will be assessed.

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.

Budget: The reasonableness of the proposed budget and the requested period of support in relation to the proposed research. The priority score should not be affected by the evaluation of the budget.

V.2. Review and Selection Process

Applications will be reviewed for completeness by the Procurement and Grants Office (PGO) and for responsiveness by the OPHR. 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 announcement will be evaluated for scientific and technical merit by an appropriate peer review group or charter study section, a Special Emphasis Panel (SEP), convened by the OPHR in accordance with the review criteria listed above. As part of the initial merit review, all applications will:

- Undergo a process in which only those applications deemed to have the highest scientific merit by the review group, generally the top half of the applications under review, will be discussed and assigned a priority score.
- Receive a written critique.
- Receive a second programmatic level review by the Office of Science, National Immunization Program.
- Undergo a peer review by a Special Emphasis Panel (SEP). The SEP will be selected from the NIH pool of scientists or recommendations from the NIP to serve as reviewers on SEPs.

Applications will be ranked for the secondary review according to scores submitted by the SEP. Only those applications deemed to have the highest scientific merit by the review group, generally the top half of the applications under review, will be discussed and assigned a priority score.

Award Criteria: Criteria that will be used to make award decisions during the programmatic review include:

- Scientific merit (as determined by peer review)
- Availability of funds
- Programmatic priorities

V.3. Anticipated Announcement and Award Dates

Award Date: August 31, 2005.

VI. Award Administration Information

VI.1. Award Notices

Successful applicants will receive a Notice of Award (NoA) from the CDC Procurement and Grants Office. The NoA shall be the only binding, authorizing document between the recipient and CDC. The NoA 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 from the Scientific Review Administrator, NIP.

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–1 Human Subjects Requirements
- AR–2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
- AR–7 Executive Order 12372
- AR–8 Public Health System Reporting Requirements
- 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–24 Health Insurance Portability and Accountability Act Requirements
- 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. 9/2004 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. Progress Toward Measures of Effectiveness.

b. Additional Information Requested by Program.

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 Specialist listed in the ''Agency Contacts'' section of this announcement.

VII. Agency Contacts

We encourage inquiries concerning this announcement.

For general questions, 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: Susan Chu, PhD, MSPH, Extramural Program Official, Centers for Disease Control and Prevention, National Immunization Program, MS E–05, 1600 Clifton Road NE., Atlanta, GA 30333, Telephone: (404) 639–8727, E-mail: *SChu@cdc.gov.*

For questions about peer review, contact: Mary Lerchen, DrPH, Scientific Review Administrator, CDC/Office of Public Health Research, One West Court Square, Suite 7000, MS D–72, Telephone: 404–371–5277, Fax: 404–371–5215, E-mail: *MLerchen@cdc.gov.*

For financial, grants management, or budget assistance, contact: Ann Cole, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, MS K–14, Atlanta, GA 30341, Telephone: 770–488–2686, E-mail: *ZLR5@cdc.gov.*

VIII. Other Information

This and other CDC funding opportunity announcements can be found on the CDC Web site, Internet address: *http://www.cdc.gov.* Click on ''Funding'' then ''Grants and Cooperative Agreements.''

Dated: May 4, 2005.

William P. Nichols,

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

[FR Doc. 05–9273 Filed 5–9–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0012]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Allergen Labeling of Food Products Consumer Preference Survey and Experimental Study on Allergen Labeling of Food Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by June 9, 2005.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Allergen Labeling of Food Products Consumer Preference Survey

Under section 903(b)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 393(b)(2)), FDA is authorized to conduct research relating to foods and to conduct educational and public information programs relating to the safety of the Nation's food supply. FDA is planning to conduct a consumer survey about allergen labeling of food products under this authority. The Allergen Labeling of Food Products Consumer Preference Survey will collect information (see table 1 of this document) to gauge the impact of certain changes to the food label with respect to information about allergenic ingredients. This data collection is needed to satisfy some of the requirements of the Food Allergen Labeling and Consumer Protection Act (FALCPA) (Public Law 108–282, title II, section 204.4), including the requirement that FDA provide data on consumer preferences in a report to Congress. In particular, section 204.4 of the FALCPA asks FDA to describe in the report ''* * *how consumers with food allergies or the caretakers of consumers would prefer that information about the risk of cross-contact be communicated on food labels as determined by using appropriate survey mechanisms.'' In addition, the survey will address other issues pertinent to allergen labeling changes mandated by the FALCPA. The data will be collected by means of a pool of people who will be screened (through self-report) for food allergy, and food allergy caregiver status. A balanced sample of 1,000 will be selected. Participation in the survey is voluntary.

Experimental Study on Allergen Labeling of Food Products

As previously stated, under section 903(b)(2) of the act, FDA is authorized to conduct research relating to foods and to conduct educational and public information programs relating to the safety of the Nation's food supply. FDA is planning to conduct an experimental study about allergen labeling of food products under this authority. The Experimental Study on Allergen Labeling of Food Products will collect information (see table 2 of this document) to gauge the impact of certain changes to the food label with respect to information about allergenic ingredients. This data collection is needed to satisfy some of the requirements of the FALCPA, including the requirement that FDA provide data on consumer preferences with regard to allergen labeling in a report to Congress. In particular, section 204.4 of the FALCPA asks FDA to describe in the report ''* * *how consumers with food allergies or the caretakers of consumers would prefer that information about the risk of cross-contact be communicated on food labels as determined by using appropriate survey mechanisms.'' The allergen labeling experiment will supplement data collected by the Allergen Labeling of Food Products Consumer Preference Survey. In addition, the experiment will address other issues pertinent to allergen labeling changes mandated by the FALCPA. The experimental study data will be collected using an Internet panel of people who will be screened (through self-report) for food allergy, and food allergy caregiver status. Participation in the allergen experimental study is voluntary.

In the **Federal Register** of January 26, 2005 (70 FR 3711), FDA published a 60-day notice requesting public comment on the information collection provisions. FDA received two comments, both from the same consortium of food allergy interested organizations: The American Academy of Allergy, Asthma & Immunology (AAAAI); the American College of Allergy, Asthma & Immunology (ACAAI); and The Food Allergy & Anaphylaxis Network (FAAN). The comments were identical and are addressed in the following paragraphs.

The comments applauded FDA's goals for the research. The comments suggested that to improve the quality of the study and analysis, the agency should do the following: (1) Consider using FAAN's membership rolls to draw the samples, (2) screen the sampling frame to maximize the likelihood of recruiting truly food allergic individuals, (3) acknowledge that some households have multiple individuals who are food allergic, (4) recognize that some individuals do not have Internet access, (5) consider using advisory labeling that is currently found in the marketplace, and (6) collaborate closely with appropriate representatives from their organizations.

The agency has considered the offer to use FAAN's membership rolls to draw the study samples and has determined that the high likelihood of bias would render results not generalizable. The agency does not agree that using FAAN's membership rolls will yield a better sample than can be acquired by using established Internet panels.

FDA will utilize two consumer Internet panels to collect data for this research. One of the advantages to using Internet panels is the small ratio between the cost of the research and the