

Officer, Air Pollution and Respiratory Health Branch, Division of Environmental Hazards and Health Effects, National Center for Environmental Health, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, Mailstop E-17, Atlanta, GA 30333, Telephone: 404-498-1033, E-mail: mmercier@cdc.gov.

For financial, grants management, or budget assistance, contact: Gary Teague, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770-488-1981, E-mail: GTeague@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."

For additional reference materials, please see Attachments I and II.

Dated: April 14, 2005.

William P. Nichols,

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

Attachment I—References

"National Asthma Training Curriculum" CD-ROM educational resource, CDC National Center for Environmental Health and the Academy of Allergy, Asthma and Immunology, August 2004.

"Potentially Effective Interventions for Asthma" <http://www.cdc.gov/asthma/interventions.htm>.

Boss, L.; Kreutzer, R.; Luttinger, D.; Leighton, J.; Wilcox, K.; and Redd, S. "The Public Health Surveillance of Asthma," *Journal of Asthma*, 38(1), 83-89, 2001.

"Framework for Program Evaluation in Public Health," *Morbidity and Mortality Weekly Report*, September 17, 1999/48(RR-11); 1-40 at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr4811a1.htm> or <http://www.cdc.gov/eval/framework.htm>.

"Surveillance of Work-Related Asthma in Selected U.S. States Using Surveillance Guidelines for State Health Departments—California, Massachusetts, Michigan and New Jersey, 1993-1995," *Morbidity and Mortality Weekly Report*, June 25, 1999/48(SS03); 1-20 at <http://www.cdc.gov/mmwr/preview/mmwrhtml/ss4803a1.htm>.

"The Role of States in a Nationwide Comprehensive Surveillance System for Work-related Diseases, Injuries and Hazards" at <http://www.cste.org/occupationalhealth.htm>.

"Minimum and Comprehensive State-Based Activities in Occupational Safety and Health," June 1995—DHHS (NIOSH) Publication No. 95-107 at <http://www.cdc.gov/niosh/95-107.html>.

"American Thoracic Society: Occupational Contribution to the Burden of Airway Disease," *American Journal of Respiratory*

and Critical Care Medicine, 167:787-797, 2003.

"Updated Guidelines for Evaluating Surveillance Systems, Recommendations from the Guidelines Working Group," *Morbidity and Mortality Weekly Report*, July 27, 2001/(50)RR-13; 1-35 at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5013a1.htm>.

Madden, J; Boss, L; Kownaski, M; Lambricht, L; Lee, C; Luttinger, D; Recer, G; Wedemeyer, C. "Guide for State Health Agencies in the Development of Asthma Programs." Atlanta, Georgia: U.S. Centers for Disease Control and Prevention, 2003.

"Guidelines for the Diagnosis and Management of Asthma," (Clinical Practice Guidelines, Guidelines for the Diagnosis and Management of Asthma. National Institutes of Health (NIH), National Heart, Lung and Blood Institute. NIH publication No. 97-4051, April 1997) at <http://www.nhlbi.nih.gov/guidelines/asthma/asthgdln.htm>.

"Key Clinical Activities for Quality Asthma Care: Recommendations of the National Asthma Education and Prevention Program." *MMWR* March 28, 2003; 52(RR06):1-84.

Strategies for addressing asthma in school settings: <http://www.cdc.gov/HealthyYouth/asthma/>.

Attachment II—BRFSS Asthma Call-Back Survey

The National Asthma Survey (NAS) is a comprehensive state/city level detailed asthma survey. It is administered by phone and includes respondents of all ages. Previously the NAS was linked to the National Immunization Survey (NIS) through the State and Local Area Integrated Telephone Survey (SLAITS) mechanism. SLAITS is a function of the National Center for Health Statistics. A full questionnaire for that survey can be viewed on the SLAITS Web site. <http://www.cdc.gov/nchs/about/major/slaits/nsa.htm>.

The initial NAS field test occurred in 2002 in Alabama, California, Illinois and Texas. This first field test did not achieve an adequate response rate level. Consequently additional field tests were implemented to determine whether procedural changes could improve the response rate. In 2003, the NAS was conducted as a field test in the same four states and also in a national sample.

There were four arms in the 2003 field test. The national sample and the state sample were the two main arms. The national sample obtains demographic information about respondents who do not have asthma in order to estimate prevalence rates. The four-state sample only solicited information from households that had a member with asthma and, consequently, prevalence rates cannot be determined. Results from comparing the four state results with the first field test will determine if obtaining prevalence rates resulted in a significantly lower response rate. Comparing the national sample with the first field test in the four states will determine if the four selected states were particularly difficult with respect to response rates as was suggested from the results from other surveys.

Each of the two main arms was also divided into a NIS-connected sample and a sample independent of the NIS procedures. Comparisons between these two secondary arms within each primary arm will determine if restrictions related to the NIS survey procedures were detrimental to the NAS response rate. In addition, several other modifications were made to simplify the selection of a single respondent from the household members.

During 2004 the data obtained were weighted and scrutinized to determine the best combination of methodological changes to ensure that quality data result from further implementation of the National Asthma Survey.

In 2005 the NAS will be implemented as a call-back survey in conjunction with the Behavioral Risk Factor Surveillance System (BRFSS) in three test states (Michigan, Minnesota and Oregon). The child selection module and the child prevalence module must be conducted at the time of the BRFSS interview. Adults and children who are identified with lifetime asthma will be called back approximately 2 weeks after the initial BRFSS telephone interview. At the time of the call-back the NAS interview will be conducted. Draft questionnaires can be obtained by contacting the Air Pollution and Respiratory Health Branch (404-498-1000). Prevalence figures for adults in all BRFSS areas (50 states, DC and 3 territories) can be obtained from the core BRFSS survey. However, the child selection module and child prevalence modules are needed for state level child prevalence estimates from BRFSS.

In 2006 funding to implement the BRFSS asthma call-back survey will be provided to BRFSS states, DC, or territories who successfully apply for that funding in conjunction with their BRFSS funding. Asthma program staff must work jointly with their state's BRFSS program coordinator when submitting request for asthma call-back funding to the National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP).

[FR Doc. 05-7889 Filed 4-19-05; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Health Education Enhancement Program

Announcement Type: Competing Continuation.

Funding Opportunity Number: RFA 05072.

Catalog of Federal Domestic Assistance Number: 93.283.

Letter of Intent Deadline: May 4, 2005.

Application Deadline: June 20, 2005.

Executive Summary: The purpose of the program is to strengthen the nation's capacity to carry out public health

activities in the area of asthma education. More specifically, the objective is to provide appropriate resources for health education of patients and others impacted by asthma.

I. Funding Opportunity Description

Authority: This program is authorized under Sections 301 and 317 of the Public Health Service Act, (42 U.S.C. 241 and 247b), as amended.

Background: Although there are many asthma educational materials which have been produced and disseminated, there remain gaps in the availability and dissemination of materials which are targeted to adults, the elderly, rural populations, non-English speaking populations, adolescents, and other underserved and disparately impacted populations.

Purpose: The purpose of the program is to strengthen the nation's capacity to carry out public health activities in the area of asthma education. The objectives are to: (1) Review and disseminate currently available asthma educational materials to reach community members on a community, local and national level; and (2) modify existing, scientifically-proven-effective asthma educational materials to make them culturally and linguistically competent for targeted populations, and disseminate these materials on a national level to families impacted by asthma, particularly working with underserved and disparately impacted populations. This program addresses the "Healthy People 2010" focus area(s) of reducing asthma hospitalizations, deaths, and improving quality of life.

Measurable outcomes of the program will be in alignment with one (or more) of the following performance goal(s) for the National Center for Environmental Health (NCEH): To reduce the number of asthma hospitalizations, deaths, and emergency department visits.

This announcement is only for non-research activities supported by CDC. If research is proposed, the application will not be reviewed. For the definition of research, please see the CDC Web site at the following Internet address: <http://www.cdc.gov/od/ads/opspoll1.htm>.

Activities: Awardee activities for this program are as follows:

- Review and disseminate currently available asthma educational materials to reach applicant organization members and other community members on a national, local, and community level. The materials must be proven effective, and in accordance with sound asthma management practices and appropriate National Asthma Education and Prevention Program (NAEPP) Guidelines.

- In cases where appropriate, asthma educational materials do not exist for populations which are underserved and a need for such materials is identified, applicants should adapt or modify existing educational materials which have been scientifically proven effective, through appropriate, published research results. Resulting materials must be accurate, user-friendly, culturally and linguistically appropriate, and be used to educate the applicant organization's members and other members of the community, or any targeted group for which a gap in currently available educational materials is identified. Literacy level and appropriate demographics of your target audience must be considered.

- Conduct interactive community outreach education at the local level, aimed at your members and community members affected by asthma.

Present a plan by which you will measure the effectiveness of your proposed activities.

Collaborate with partners, including CDC and appropriate asthma education organizations, to ensure that best practices are used in the adaptation/modification and dissemination of asthma education materials for your target audiences.

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:

- Collaborate with recipients in the modification and adaptation of existing educational materials which have been scientifically proven effective through appropriate published research results. Ensure coordination of this activity among all recipients and facilitate information sharing.

- Review recipients' identification of currently available educational materials and gap analysis; and ensure coordination of this activity among all recipients, including information sharing and elimination of duplication of efforts among recipients.

- Facilitate and coordinate meetings to bring together national groups as collaborators, where appropriate.

- Collaborate with recipients on the development of an appropriate evaluation plan which measures the effectiveness of recipient activities involved in each step indicated, and approve the plan.

- Coordinate recipient activities with asthma education partners to ensure duplication of activities and efforts does not occur.

II. Award Information

Type of Award: Cooperative Agreement. CDC involvement in this program is listed in the Activities Section above.

Fiscal Year Funds: 2005.

Approximate Total Funding: \$225,000 to \$300,000. (This amount is an estimate, and is subject to availability of funds.)

Approximate Number of Awards: Three.

Approximate Average Award: \$75,000 to 100,000. (This amount is for the first 12-month budget period, and includes both direct and indirect costs.)

Floor of Award Range: None.

Ceiling of Award Range: \$100,000. (This ceiling is for the first 12-month budget period.)

Anticipated Award Date: August 31, 2005.

Budget Period Length: 12 months.

Project Period Length: 5 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 nonprofit organizations such as:

- Public nonprofit organizations.
- Private nonprofit organizations.
- Community-based organizations.
- Faith-based organizations.

Assistance will be provided only to applicants that are well-established, national, non-profit organizations with experience in the development and dissemination of asthma educational materials; and whose membership includes families of adults or children with asthma, or others affected by the disease.

The justification for the foregoing limitation is the need for the applicant to have immediate access to a national audience, and existing expertise in the modification and dissemination of asthma educational materials to community members impacted by asthma, to insure they may access the greatest number of people in the shortest period of time.

To be eligible, applicants must:

1. Demonstrate that your organization's mission is explicitly committed to improving the lives of families impacted by asthma, or other similar lung diseases, through the

provision of timely, accurate, and useful information about the disease and how it can be controlled. You must have experience providing asthma education to a nationwide audience. The foregoing may be demonstrated by submission of your charter, articles of incorporation, or other governing documents.

2. Demonstrate that your organization is non-profit and recognized as tax-exempt under Section 501(c)(3) of the Internal Revenue Code. This may be demonstrated through inclusion of your Internal Revenue Service determination letter.

3. Demonstrate that your organization has the capacity for and experience in providing educational services to families with asthma on a nationwide basis. This may be demonstrated through letters of support.

4. Demonstrate that your organization has the capacity for and experience providing educational services to families or a national network of local organizations. This may be demonstrated through a letter from your organization's leadership, which describes your national network/membership (number of members and national coverage of the membership).

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 special 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.

IV. Application and Submission Information

IV.1. Address To Request Application Package

To apply for this funding opportunity use application form PHS 5161-1.

CDC strongly encourages you to submit your application electronically by utilizing the forms and instructions posted for this announcement at <http://www.grants.gov>.

Application forms and instructions are available on the CDC Web site, at the following Internet address: <http://www.cdc.gov/od/pgo/forminfo.htm>.

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 Submission

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

- Maximum number of pages: One.
- Font size: 12-point un-reduced.
- 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:

- Name and address of organization.
- Name, address, telephone number, fax number and e-mail address of the organization's primary contact for writing and submitting the application.
- A brief summary of the proposed project.

Application: You must submit a project narrative with your application forms. The narrative must be submitted in the following format:

- Maximum number of pages: 25 pages (not including attachments for purposes of establishing eligibility). If your narrative exceeds the page limit, only the first pages which are within the page limit will be reviewed.
- Font size: 12 point un-reduced.
- Double spaced.
- Paper size: 8.5 by 11 inches.
- Page margin size: One inch.
- Printed only on one side of page.
- Pages shall be numbered sequentially, including your narrative and any appendices.
- Held together only by rubber bands or metal clips; not bound in any other way.

Your narrative should address activities to be conducted over the entire project period, and must include the following items in the order listed:

- History and Experience.
 - Proposed Program.
 - Evaluation Plan.
 - Facilities, Staff and Resources.
 - Budget and Justification.
 - Documentation of eligibility, as follows:
 - a. Submit your charter, articles of incorporation, or other governing documents to demonstrate your organization's mission is explicitly committed to improving the lives of families impacted by asthma, or other similar lung diseases, through the provision of timely, accurate, and useful information about the disease and how it can be controlled.
 - b. Submit your Internal Revenue Service determination letter which will demonstrate your organization is non-profit and recognized as tax-exempt under Section 501(c)(3) of the Internal Revenue Code.
 - c. Submit letters of support, which will demonstrate that your organization has the capacity for and experience in providing educational services to families with asthma on a nationwide basis.
 - d. Submit a letter from your organization's leadership, which describes your national network/membership (number of members and national coverage of the membership).
- The budget justification and documentation to establish eligibility will NOT be counted in the stated page limit.
- Additional information may be included in the application appendices. The appendices will not be counted toward the narrative page limit. This additional information includes:
- Curriculum Vitae (of key staff positions).
 - Letters of Support.
- 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. 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/pubcommnt.htm>.
- If your application form does not have a DUNS number field, please write your DUNS number at the top of the first page of your application, and/or include your DUNS number in your application cover letter.
- 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: May 4, 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 20, 2005.

Explanation of Deadlines:

Applications must be received in the CDC Procurement and Grants Office by 4 p.m. eastern time on the deadline date.

You may submit your application electronically at <http://www.grants.gov>. Applications completed online through Grants.gov are considered formally submitted when the applicant organization's Authorizing Official electronically submits the application to <http://www.grants.gov>. Electronic applications will be considered as having met the deadline if the application has been submitted electronically by the applicant organization's Authorizing Official to Grants.gov on or before the deadline date and time.

If you submit your application electronically with Grants.gov, your application will be electronically time/date stamped, which will serve as receipt of submission. You will receive an e-mail notice of receipt when CDC receives the application.

If you submit your 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 carrier's guarantee. If the documentation verifies a carrier problem, CDC will consider the submission as having been received by the deadline.

If you submit a hard copy application, 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, 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.

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 submission 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.

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 may not be used for research.
- Reimbursement of pre-award costs is not allowed.

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

Guidance for completing your budget can be found on the CDC Web site, at the following Internet address: <http://www.cdc.gov/od/pgo/funding/budgetguide.htm>.

IV.6. Other Submission Requirements

LOI Submission Address: Submit your LOI by express mail, delivery service, fax, or e-mail to: Sheri Disler, Centers for Disease Control and Prevention, National Center for Environmental Health, 1600 Clifton Road, MS E-17, Atlanta, GA 30303; telephone: 404-498-1018, Facsimile: 404-498-1088, e-mail address: SDisler@cdc.gov.

Application Submission Address: CDC strongly encourages applicants to submit electronically at: <http://www.grants.gov>. You will be able to download a copy of the application package from <http://www.grants.gov>, complete it offline, and then upload and

submit the application via the Grants.gov site. E-mail submissions will not be accepted. If you are having technical difficulties in Grants.gov, they can be reached by e-mail at http://www.support@grants.gov or by phone at 1-800-518-4726. The Customer Support Center is open from 7 a.m. to 9 p.m. eastern time, Monday through Friday.

CDC recommends that you submit your application to Grants.gov early enough to resolve any unanticipated difficulties prior to the deadline. You may also submit a back-up paper submission of your application. Any such paper submission must be received in accordance with the requirements for timely submission detailed in Section IV.3. of the grant announcement. The paper submission must be clearly marked: "BACK-UP FOR ELECTRONIC SUBMISSION."

The paper submission must conform to all requirements for non-electronic submissions. If both electronic and back-up paper submissions are received by the deadline, the electronic version will be considered the official submission.

It is strongly recommended that you submit your grant application using Microsoft Office products (e.g., Microsoft Word, Microsoft Excel, etc.). If you do not have access to Microsoft Office products, you may submit a PDF file. Directions for creating PDF files can be found on the Grants.gov Web site. Use of file formats other than Microsoft Office or PDF may result in your file being unreadable by our staff.

Or

Submit the original and two hard copies of your application by mail or express delivery service to: Technical Information Management—RFA 05072, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341.

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.

Your application will be evaluated against the following criteria:

1. History and Experience (30 Points)

The extent to which the proposal clearly demonstrates the applicant's solid reputation and history of serving families affected by asthma. The proposal should demonstrate that the applicant has a broad range of knowledge and expertise in the field of asthma, as well as significant years of experience in the dissemination and application of this knowledge and expertise. The proposal should also demonstrate that the applicant's membership is comprised of families affected by asthma, and that this membership is national in scope.

2. Proposed Program (30 Points)

The extent to which the proposal clearly demonstrates the applicant's understanding of the issues surrounding asthma and asthma education activities, and addresses gaps in the current state of asthma educational materials and activities. The proposal should demonstrate that the applicant has a clear understanding of the gaps and needs, and has a clear plan of activities, which will address these gaps. The applicant must demonstrate that their educational materials are in adherence to the NAEPP guidelines and, when these guidelines are updated, that materials are appropriately updated.

3. Evaluation Plan (30 Points)

The extent to which the applicant describes a realistic plan to accurately measure the effectiveness of their activities, and a plan to implement the quality improvements indicated by this method over the life of the project. This may include a discussion of efforts undertaken to measure the effectiveness of the applicant's existing outreach and educational activities.

4. Facilities, Staff and Resources (10 Points)

The extent to which the applicant can provide adequate facilities, staff, collaborators, and resources to accomplish the proposed goal(s) and objectives during the project period. The extent to which the applicant demonstrates staff and collaborator availability, expertise, previous experience, and capacity to perform the undertaking successfully.

5. Budget (Not Scored)

The extent to which the proposal demonstrates appropriateness and justification of the requested budget relative to the activities proposed.

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 NCEH. 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. The objective review panel participants will be CDC employees, all of whom work outside the NCEH.

Applications will be funded in order by score and rank determined by the review panel.

V.3. Anticipated Announcement and Award Dates

Anticipated award date is 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-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-23 States and Faith-Based Organizations.
- AR-24 Health Insurance Portability and Accountability Act Requirements.

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>.

An additional Certifications form from the PHS5161-1 application needs to be included in your Grants.gov electronic submission only. Refer to <http://www.grants.gov/od/pgo/funding/PHS5161-1Certificates.pdf>. Once the form is filled out, attach it to your Grants.gov submission as Other Attachment Forms.

VI.3. Reporting Requirements

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

1. Interim progress report, due 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. Measures of Effectiveness.
 - f. Additional Requested Information.
2. Annual progress report, due 30 days after the end of the budget period. The annual progress report must contain the following elements:
 - a. Current Budget Period Activities Objectives.
 - b. Lessons Learned.
3. Financial status report and annual progress report, no more than 90 days after the end of the budget period.
4. 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

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 program technical assistance, contact: Sheri Disler, Project Officer, 1600 Clifton Road, NE, MS E-17, Atlanta, GA 30303; telephone: 404-498-1018, e-mail: SDisler@cdc.gov.

For financial, grants management, or budget assistance, contact: Edna Green, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341; telephone: 770-488-2743, e-mail: EGreen@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: April 14, 2005.

William P. Nichols,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N-0486]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Experimental Study of Health Claims on Food Packages

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 May 20, 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.

Experimental Study of Health Claims on Food Packages

The authority for FDA to collect the information derives from the FDA

Commissioner's authority, as specified in section 903(d)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 393(d)(2)).

To help consumers reduce their risk of disease and improve their health by making sound dietary decisions, in the **Federal Register** of November 25, 2003 (68 FR 66040), FDA issued an advance notice of proposed rulemaking (ANPRM) to request comments on various issues related to health claims on conventional food and dietary supplement labels. One of the issues that FDA raised in the ANPRM related to whether the wording of a health claim needs to refer to the substance (a component of food, e.g., a nutrient) that is the basis of the claim. (Hereinafter, the term "health claim" will refer only to a claim meeting the standard of significant scientific agreement or, in other words, an FDA-authorized claim.) For instance, in the example of the calcium-osteoporosis claim ("Calcium may reduce the risk of osteoporosis"), FDA currently requires that the substance that is the basis of the claim (in this case, calcium) be included in the wording of the claim (21 CFR 101.72). The requirement that the substance in a health claim be included in the wording of the claim was motivated by FDA's experience that most substances that are the subject of an authorized health claim are, like calcium, substances that can be found in a number of foods. Therefore, FDA requires that health claims refer to the common substance to assist consumers in their understanding of the nature of the diet-health relationship and, more importantly, to help consumers recognize that they can construct healthy diets by using a variety of foods that contain the substance.

FDA requests comments on the usefulness of such statements (e.g., "Calcium-rich foods, such as yogurt, may reduce the risk of osteoporosis") versus "food-specific" claims that do not specify the food component (e.g., "Yogurt may reduce the risk of osteoporosis"). How consumers respond to the two kinds of statements can suggest how the explicit mention of a food component in a claim affects dietary choices which, in turn, informs any policy initiative(s) that FDA may undertake in the future to provide information to consumers to help them make informed food choices.

The purpose of the proposed collection of information is to enhance FDA's understanding of consumer responses to health claims and inform any policy initiative(s) that FDA may undertake in the future. The information will be used to assess what differences,

if any, the inclusion of the food component in a health claim makes in the following areas: (1) Consumer recognition of the food component underlying a diet-disease relationship; (2) consumer recognition that, in addition to the food product that carries the claim, there are other foods from which they can obtain the food component; and (3) consumer perceptions of, and attitudes toward, the food.

The proposed collection of information is a controlled randomized experimental study. The study will use a 6 x 3 within-subjects design (6 front-panel health claims/health messages x 3 diet-disease relationships), with participants randomly assigned to experimental conditions. In total, the study will examine 18 experimental conditions (6 front-panel health claim/health message conditions x 3 diet-disease relationships), each condition is a combination of a front-panel condition and a diet-disease relationship.

The term "health message" refers to nutrient content claims, structure/function claims, and dietary guidance statements. Prior knowledge of foods, components of food (e.g., nutrients), and risks will be measured; such prior knowledge will serve as covariates in the analysis. There are two independent variables, type of front-panel health claim/health message and type of diet-disease relationship. Health claim/health message conditions include the following items:

1. A "food-specific" health claim, e.g., "Yogurt may reduce the risk of osteoporosis;"
2. A "nutrient-specific" health claim, e.g., "Calcium-rich foods, such as yogurt, may reduce the risk of osteoporosis;"
3. A nutrient content claim, e.g., "a good source of calcium;"
4. A structure/function claim, e.g., "Helps promote bone health;"
5. A dietary guidance statement, e.g., "Dairy products may reduce the risk of osteoporosis;" and
6. No health claim/health message. Claims on food labels must be truthful and nonmisleading as required under sections 201(n) and 403(a)(1) of the act (21 U.S.C. 321(n) and 343(a)(1)).

Health messages other than the two health claims are included solely for methodological purposes. The "no health claim/health message" condition is included to examine what consumers already know about nutrients or food sources, even when neither of them is mentioned on a label. Health messages are frequently found on food product packages and provide consumers various amounts of information about