

be an element of evaluation. Your application will be evaluated against the following criteria:

1. Methods and Technical Approach (30 points)

a. Does the applicant clearly and succinctly describe the steps to be taken in the planning and implementation of the proposed cooperative agreement?

b. Are the methods to be used to carry out the responsibilities of the proposed cooperative agreement feasible and explained in sufficient detail?

2. Project Management and Staffing (30 points)

a. Does the applicant describe a project management and staffing plan, and demonstrate sufficient knowledge, expertise, and other resources required to perform the responsibilities in this project?

b. Does the applicant describe the staff qualifications and time allocations of key personnel to be assigned to this project, facilities and equipment, and other resources available for performance of this project?

3. Goals and Objectives (20 points)

a. Does the applicant clearly describe an understanding of the objectives of this project, the relevance of the proposal to the stated objectives, and any unique characteristics of the populations to be studied?

b. Are the goals and objectives measurable, specific, and achievable?

4. Evaluation Plan (20 points)

Does the applicant describe the schedule for accomplishing the activities to be carried out in this project and methods for evaluating the accomplishments?

5. Budget (reviewed, but not scored)

Is the proposed budget reasonable, clearly justified, and consistent with the intended use of funds?

6. Performance Measures (reviewed, but not scored)

Is the application consistent with the Government Performance and Results Act of 1993 (<http://www.whitehouse.gov/omb/mgmt-gpra/gplaw2m.html>)?

V.2. Review and Selection Process

Applications will be reviewed for completeness by the Procurement and Grants Office (PGO) staff, and for responsiveness by PHPPPO. 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.

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-10 Smoke Free Workplace Requirements;
- AR-11 Healthy People 2010;
- AR-12 Lobbying Restrictions,;
- AR-15 Proof of Non-Profit Status.

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 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 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: Joe Boone, Ph.D., Associate Director for Science, Division of Laboratory Systems, Public Health Practice Program Office, 4770 Buford Hwy., NE., Atlanta, GA 30341-3717, Telephone: (770) 488-8080, fax: (770) 488-8282, e-mail: dboone@cdc.gov.

For financial, grants management, or budget assistance, contact: Sharon Robertson, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770-488-2748, e-mail: sqr2@cdc.gov.

VIII. Other Information

Web site for information about 2003 Quality Institute and related activities: <http://www.phppo.cdc.gov/mlp/qiconference/>.

Dated: June 16, 2004.

William P. Nichols,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772-76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 69 FR 17166-17167, dated April 1, 2004) is amended to reorganize the Division of Health Interview Statistics, National Center for Health Statistics.

Section C-B, Organization and Functions, is hereby amended as follows:

Delete in its entirety the title and functional statement for the *Division of Health Interview Statistics (CS7)* insert the following:

Division of Health Interview Statistics (CS7). The Division of Health Interview Statistics plans and administers

complex data collection systems and analytic programs and conducts a program of methodologic and substantive public health research activities based on the collection of data from nationwide and special health interview surveys. (1) Participates in the development of policy, long-range plans, and programs of NCHS; (2) plans, directs, and coordinates the health interview statistics program of NCHS; (3) administers Division programs comprised of national health interview surveys, longitudinal surveys, population-based telephone surveys, targeted follow-up studies, and national and subnational surveys on selected health topics; (4) conducts research on data collection and estimation methodology, survey methodology, questionnaire design, data quality and reliability, and statistical computation related to health and health status assessment; (5) analyzes data and publishes reports on the prevalence and incidence of disease and associated disabilities, health status, health-related behaviors, utilization of health care resources, health insurance status, and other health and well-being related topics; (6) conducts multidisciplinary research directed toward development of new scientific knowledge in areas related to health and health care, population demographics, economics, epidemiology, statistics, and disability; (7) performs innovative theoretical and experimental investigations of the content of health interview surveys; (8) develops sophisticated approaches to making health interview statistics data available to users, including techniques to avoid disclosure of confidential data; (9) conducts descriptive analyses and sophisticated multivariate analyses that integrate data across multiple surveys or data sets; (10) designs, develops, and implements state-of-the-art computing systems for collecting, storing, and retrieving health interview statistics data and for subsequent analysis and dissemination; (11) applies computer systems and software in its programs, consistent with NCHS and CDC information technology requirements; (12) incorporates novel system improvement efforts to maintain timeliness, efficiency, cost effectiveness, and accuracy of data systems over multiple years; (13) conducts methodological research on the utilization, evaluation, and presentation of health interview statistics; (14) produces and publishes a wide variety of health interview statistics reports, papers, and tabulations in multiple formats as well as makes presentations on analyses of such data; and (15)

develops and sustains collaborative partnerships with, and provides expert advice and technical assistance to NCHS, CDC, and DHHS and externally with public, private, domestic and international entities on issues regarding health interview statistics data.

Office of the Director (CS71). (1) Participates in the development of policy, long-range plans, and programs of NCHS; (2) provides leadership for the design, development, conduct, and statistical evaluation of the Division's data systems; (3) oversees the analysis and dissemination of national and subnational health interview statistics through national health interview statistics surveys, supplements, and customized population surveys; (4) coordinates the planning and production activities of the Division including data collection, information technology, and data dissemination systems; (5) directs, plans, and monitors the scientific integrity and relevance to public health of the Division's data, publications, services, and other products; (6) develops and administers a research, analytic, and methodological program in health interview statistics; (7) conducts theoretical and experimental research to improve the usefulness of the Division's statistics and data to policymakers, researchers, and academia; and (8) provides advice and leads development of collaborative partnerships within NCHS, CDC, and DHHS, and externally with public, private, domestic and international entities on issues regarding health interview statistics and the manner in which statistics may impact policy issues.

Delete the title and functional statement for the *Systems and Programming Branch (CS72)*, and insert the following:

Data Production and Systems Branch (CS72). (1) Conducts research into the design, development, deployment, and administration of survey and information technology systems to collect, process, and disseminate national health interview survey data; (2) develops system improvement plans and strategies to insure timely, cost-effective, accurate, and confidential data collection and production systems; (3) performs systems analysis and computer programming of health interview statistics data, employing state-of-the-art information technologies in support of data collection, processing, maintenance, analysis, and dissemination activities; (4) develops and adopts computer technologies, data architectures, security infrastructure, and database management for health

interview statistics systems that are consistent with NCHS and CDC IT requirements; (5) develops and implements data collection and production standards for the Division's surveys; (6) provides planning for utilization of evolving telecommunication, data access, and network technologies in Division survey efforts; (7) conduct studies and analyses of data collection, processing, and dissemination systems to insure data confidentiality; (8) designs and implements computer applications to produce final edited and imputed health interview survey data and statistics; (9) produces health statistics reports and tabulations of data from health interview surveys in multiple formats; and (10) provides consultation and expert technical assistance NCHS-wide as well as to a broad range of agencies, institutions, federal, local, and international governments, researchers, and individuals regarding systems design and administration for health interview statistics technology systems.

Delete in their entirety the title and functional statement for the *Survey Planning and Development Branch (CS73)* and insert the following:

Survey Planning and Special Surveys Branch (CS73). (1) Establishes the design and content of the national health interview surveys and subnational special surveys in response to public health priorities; (2) converts identified data needs into research, development, and evaluation activities and related public health information; (3) designs and conducts methodological, analytical, developmental, and evaluation studies of health interview survey processes, questions, and data; (4) performs theoretical and experimental research on the design and content of the health interview survey in order to improve the timeliness, availability, and quality of the health interview statistics data; (5) plans and conducts special customized population surveys such as the State and Local Area Integrated Telephone Survey (SLAITS) in order to obtain timely state and smaller-area data as well as national data relevant to public health; (6) collaborates with other NCHS programs and through contracts, grants, and interagency agreements with outside sponsors of surveys for the development and implementation of survey questions and data; (7) publishes and presents results of methodological, analytical, developmental, and evaluation studies of special population surveys and data; (8) serves as the NCHS resource on special population surveys data and their use in addressing critical public health issues; and (9) provides

consultation and technical assistance to a wide range of researchers and institutions at the state, national, and international levels, addressing the definitions, needs, and uses for national and subnational health interview statistics and data.

Delete in their entirety the title and functional statement for the *Data Analysis Branch (CS74)* and insert the following:

Data Analysis and Quality Assurance Branch (CS74). (1) Conducts research and analysis on topics relevant to public health using National Health Interview Survey (NHIS) data; (2) plans, develops, and implements analytic techniques and guidelines to assure data quality standards for Division surveys and supplements; (3) prepares scientific papers and presentations on the health status of the population, broad health trends, and characteristics of persons with health problems using data from the NHIS; (4) converts identified health interview statistics data needs into research, development, and evaluation activities; (5) conducts descriptive analyses as well as multivariate analyses that integrate data across multiple surveys or data sets; (6) administers analytic and scientific peer review of manuscripts produced from data collected in the Division's programs; (7) develops and implements a data dissemination plan to address needs of researchers; (8) serves as the NCHS resource on health interview survey data and their use in assessing the prevalence and incidence of disease and associated disabilities, health status, health related behaviors, health insurance status, and other health and well-being related topics; (9) provides interpretations and recommendations regarding public health issues as a result of data analyses from the NHIS; and (10) provides consultation, technical assistance, and liaison to academia, other research groups, and State, Federal, and international entities concerning the development, uses, and dissemination of health interview survey data.

Delete in their entirety the title and functional statement for the *Special Population Surveys Branch (CS75)*.

Dated: June 6, 2004.
William H. Gimson,
Chief Operating Officer, Centers for Disease Control and Prevention (CDC).
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N-0079]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Specific Requirements on Content and Format of Labeling for Human Prescription Drugs of Geriatric Use Subsection in the Labeling

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 July 22, 2004.

ADDRESSES: The Office of Management and Budget (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: Karen L. Nelson, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

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.

Specific Requirements on Content and Format of Labeling for Human Prescription Drugs of Geriatric Use Subsection in the Labeling—(OMB Control Number 0910-0370)—Extension

Section 201.57(f)(10) (21 CFR 201.57(f)(10)) requires that the "Precautions" section of prescription drug labeling must include a subsection on the use of the drug in elderly or geriatric patients (aged 65 and over). The information collection burden imposed by this regulation is necessary to facilitate the safe and effective use of prescription drugs in older populations. The geriatric use subsection enables physicians to more effectively access geriatric information in physician prescription drug labeling.

Section 201.57(f)(10) requires that a specific geriatric indication, if any, that is supported by adequate and well-controlled studies in the geriatric population must be described under the "Indications and Usage" section of the labeling, and appropriate geriatric dosage must be stated under the "Dosage and Administration" section of the labeling. The "Geriatric use" subsection must cite any limitations on the geriatric indication, need for specific monitoring, specific hazards associated with the geriatric indication, and other information related to the safe and effective use of the drug in the geriatric population. The data summarized in this subsection of the labeling must be discussed in more detail, if appropriate, under "Clinical Pharmacology" or the "Clinical Studies" section. As appropriate, this information must also be contained in "Contraindications," "Warnings," and elsewhere in "Precautions." Specific statements on geriatric use of the drug for an indication approved for adults generally, as distinguished from a specific geriatric indication, must be contained in the "Geriatric use" subsection and must reflect all information available to the sponsor that is relevant to the appropriate use of the drug in elderly patients. These statements are described further in § 201.57(f)(10).

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
201.57(f)(10) NDAs	73	1.48	108	8	864