

open season scheduled for Spring 1999. In the interim, we plan to incorporate MMS in the current schedule as an add-on or "enhanced service" as announced previously in the **Federal Register**. To use the add-on (i.e., "enhanced service"), however, a customer agency would be required to purchase MMS as part of a total relocation services package, and would be limited to the three vendors now on schedule. While such an approach would meet the needs of a small number of Federal activities that buy the entire package of relocation services (real estate services, mortgage assistance, etc.) customers interested in acquiring only MMS would not have access to the services.

After having carefully weighed all the issues, we have concluded that for the immediate future we can best satisfy customer needs and meet industry concerns by continuing to provide MMS through the HTOS until October 31, 1999, with the clear expectation of adding MMS to the Governmentwide Employee Relocation Services Schedule as a separate service during the next open season scheduled for Spring 1999.

Under this plan, agencies that currently produce MMS under the HTOS will enjoy uninterrupted service, and agencies that wish to procure a more comprehensive package of relocation services, including MMS, will be able to do so in the very near future under the schedule. Carrier and non-schedule-broker MMS providers will be able to continue offering service under the HTOS until the next open season when they will have opportunity to compete and transition to the schedule. The broker MMS providers currently on schedule also will be able to continue offering service under the HTOS until the open season when MMS will become a separate procurement item on the schedule.

As stated in the **SUMMARY** paragraph above, this inclusive approach will allow GSA to continue meeting customer needs and address concerns raised by interested industry representatives while we transition MMS to a FAR contract procurement method.

In anticipation of favorable reaction to this inclusive plan and in an effort to keep the household goods program on target, we plan to immediately proceed with issuance of an RFO allowing both general transportation and MMS providers to file new rates for November 1, 1998, implementation (or as soon thereafter as realistically possible). Under the described plan, the new rates would be effective until October 31, 1999.

Dated: July 13, 1998.

**Janice Sandwen,**

*Director, Travel and Transportation Management Division.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[Announcement 98103]

#### Cooperative Agreement To Study Consumer Demand for Food Safety; Notice of Availability of Funds for Fiscal Year 1998

##### A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1998 funds for a cooperative agreement to study consumer demand for food safety. This announcement is related to the "Healthy People 2000" priority area of Food and Drug Safety.

The purpose of the program is to contribute to the education of the U.S. public with respect to the risk of foodborne illness and to available public and private efforts to reduce that risk, and evaluate the methods used in economic evaluation of interventions designed to improve food safety. There are five objectives to the program. The recipient will address the first two objectives in combination with any or all of the other three objectives.

The first objective of the study is to develop a program designed to educate a nationally representative sample of consumers about the risks of food borne pathogen consumption at home and retail establishments, and various collective and private means of reducing these risks. As part of the educational program, consumers will be questioned about their own food safety practices and their perceptions of the effectiveness of those practices. They will be informed of food industry measures that are intended to maintain the safety of the food supply and of safety measures they can implement at home in food storage, preparation, and consumption.

The second objective is to obtain an empirical estimate of the value consumers place on reducing the risk associated with a specific food borne illness for which interventions already exist.

The third and fourth objectives are designed to address the development, refinement, and evaluation of the

elicitation methods used in this type of evaluation. For example, it is not well understood how sensitive consumers are to small changes in the probability of rare health-related events and how they process probability information when forming their values of reduced risk of adverse health outcomes.

Therefore, the third objective is to model the process by which consumers assess such changes in probability and risk, and how they use that assessment in forming values. The validity of the model will also be evaluated.

The fourth objective is to test whether the presentation of distinct pathogen-specific and symptom-specific scenarios result in different consumer valuations. In conducting economic evaluations of health programs, it is important to be certain about what is being valued: Do consumers value reduction of risk associated with a specific pathogen or do they value reduction of the risk of experiencing the symptoms of food borne pathogens in general. Specifically, are consumers concerned about the cause of the illness, or just whether they contract the illness?

The fifth objective is to examine how alternative combinations of private and collective risk reduction strategies affect consumer valuation of safer food. Consumers already have a certain amount of control over the risk of food borne illness. There are many strategies that can be used in preparation either in the home or at a food service establishment. In addition, there are producer and processor strategies that can improve the safety of food before it arrives at the final consumer.

##### B. Eligible Applicants

Applications may be submitted by public and private nonprofit organizations and by governments and their agencies; that is, universities, colleges, research institutions, hospitals, other public and private nonprofit and State and local governments or their bona fide agents.

**Note:** Public Law 104-65 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, cooperative agreement, contract, loan, or any other form.

##### C. Availability of Funds

Approximately \$150,000 is available in FY 98 to fund one award. It is expected that the award will begin on or about September 30, 1998, and will be made for a 12-month budget period within a project period of up to 5 years. Budgets for periods 2-5 should be submitted at a level of \$200,000 per

year. Funding estimates are subject to change.

Continuation awards during the approved project period are subject to the availability of funding and performance as evidenced by required progress reports.

#### **D. Program Requirements**

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under 1. (Recipient Activities), and CDC will be responsible for the activities under 2. (CDC Activities).

##### *1. Recipient Activities*

a. Develop research plan and implement a procedure to collect data for a nationally representative sample of consumers regarding food safety practices and valuation of reduced risk of food borne illness.

b. Provide food safety education to the sample of interviewed consumers.

c. Develop, estimate, and evaluate an economic model of consumer valuation of reduced risk of food borne illness using the sample data.

d. Develop, implement, and evaluate a model of how consumers process risk reduction information when forming values and incorporate that model in the estimation of consumer valuation of reduced risk of food borne illness.

e. Develop, implement, and evaluate a means of testing the effect of illness presentation, whether pathogen- or symptom-specific, on consumer valuation of reduced risk of food borne illness.

f. Develop, implement, and evaluate a means of testing the effect of alternative combinations of private and collective risk reduction strategies on consumer valuation of reduced risk of food borne illness.

g. Evaluate and analyze data.

h. Disseminate findings to peer-reviewed publications and public information sources.

##### *2. CDC Activities*

a. Provide technical and subject-matter assistance in study design, data collection, modeling, consumer education, and data evaluation and analysis activities.

b. Assist in dissemination of findings.

c. Provide up-to-date scientific information and activities of other projects in the area.

#### **E. Application Content**

Use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections to develop the application content. Your application will be evaluated on the

criteria listed, so it is important to follow them in laying out your program plan. The narrative should be no more than 30 double-spaced pages, printed on one side, with one inch margins, and un-reduced font.

##### *1. Executive Summary*

Provide a clear, concise written summary of the following: (a) Statement of need; (b) major goals, objectives, and activities of the proposed project; (c) operational plan; (d) capability of applicant; and (e) estimated cost of the project including the requested amount.

##### *2. Table of Contents*

##### *3. Statement of Need*

Describe the role of the project in providing food safety education to consumers and valuing food safety improvement, including information on the chosen intervention and the risk of and health and economic consequences of the associated pathogen.

##### *4. Goals and Objectives*

Establish and submit short term (1 year) and long term (5 year) objectives for the project phases included in the application. Objectives must be specific, measurable, time-phased, and feasible.

##### *5. Operational Plan*

a. Submit a plan to develop the project from presenting educational food safety information to assessing attributes to be included in studies and the valuation methods and design of the data collection process.

b. Submit a time schedule for all activities to be carried out in the first year including the responsible staff for each phase of the project. Describe further activities if additional funding becomes available in future years.

c. Describe procedures to disseminate the research findings through presentation and publication in appropriate form and provide necessary reports as required by the notice of award.

##### *6. Capability*

a. Identify and describe the project staff, their qualifications and experience in the areas of economic valuation of nonmarketed goods/services and food safety and their degree of availability under a resultant agreement, and association with the applicant. Include the curriculum vitae for the key project staff in the supporting materials of the appendix.

b. Identify and describe the capacity to collect nationally representative consumer data and to provide educational food safety information as a major component of the data collection

process. Provide written commitments from appropriate public/private organizations expected to support activities of the project.

##### *7. Project Evaluation*

Submit a plan to evaluate the project that assesses the extent to which:

a. The research was designed for addressing the delivery of consumer food safety information and the specific food safety problem.

b. Survey and results were validated and pretested.

c. Data were disseminated through periodic reports, presentations, and publication.

##### *8. Budget*

##### *9. Supporting Materials*

#### **F. Submission and Deadline**

The original and 2 copies of the application PHS Form 5161-1 (revised 5/96) must be submitted to David Elswick, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E-13, Atlanta, GA 30305, on or before August 21, 1998.

**Deadlines:** Applications shall be considered as meeting the deadline above if they are either: (1) Received on or before the deadline date; or (2) sent on or before the deadline date and received in time for submission to the independent review group. (Applicants should request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

#### **G. Evaluation Criteria**

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

##### *1. Problem Identification (5 Percent)*

a. Evidence of the importance of the problem.

b. Evidence of the effectiveness of the proposed food safety intervention to be evaluated.

##### *2. Research Design (25 Percent)*

Evidence that the research design is appropriate for the project.

##### *3. Capability (30 Percent)*

a. Evidence that key project staff and/or organization possesses recent experience in economic evaluation. More specifically, the extent to which the principal investigator has the appropriate educational background for

implementation of this project. For example, a doctoral degree in economics or behavioral science with experience in the design and implementation of large-scale data collection processes and valuation of nonmarketed goods and services.

b. Evidence of organizational capacity for large-scale data collection.

c. Evidence of ability to cooperate in interorganizational and interdisciplinary settings.

#### 4. Strategic Plan (25 Percent)

a. The objectives of the project are appropriate, feasible, and time-appropriate for the project.

b. The extent to which the multiple objectives of the project can be accomplished within the first year and how further objectives can be met in subsequent years.

#### 5. Program Evaluation (10 Percent)

a. The extent to which the applicant proposes a strategy of ongoing evaluation and feedback for this project.

b. The adequacy of the applicant's plan to evaluate the overall effectiveness and success of the project.

#### 6. Women and Racial and Ethnic Minorities in Research (5 Percent)

The extent to which the applicant addresses that they have met the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research. This includes: (a) The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation; (b) The proposed justification when representation is limited or absent; (c) A statement as to whether the design of the study is adequate to measure differences when warranted; (d) 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.

#### 7. Budget (not Scored)

The extent to which the applicant describes the total amount of funds requested in each of the object class categories and clearly links the budget items to objectives and activities proposed for the budget period.

#### 8. Human Subjects (not Scored)

The extent to which the applicant has addressed necessary human subjects protections.

### H. Other Requirements

Technical Reporting Requirements: Provide CDC with the original plus two copies of

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

2. Financial Status Report is required within 90 days of each budget period.

3. Final financial status report and performance report are required within 90 days after the end of the project period.

*Send all reports to:* David Elswick, Grants Management Specialist Grants Management Branch, Procurement and Grants Office Centers for Disease Control and Prevention, (CDC) Room 300, 255 East Paces Ferry Road, NE., Mailstop E-13 Atlanta, GA 30305-2209.

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

AR98-1 Human Subjects Requirements

AR98-2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research

AR98-9 Paperwork Reduction Act Requirements

AR98-10 Smoke-Free Workplace Requirements

AR98-11 Healthy People 2000

AR98-12 Lobbying Restrictions

### I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under the Public Health Service Act, section 317(k)(2) 42USC247247(b)(k)(2). The Catalog of Federal Domestic Assistance number assigned to this project is 93.283.

### J. Where To Obtain Additional Information

To receive additional written information call 1-888-GRANTS4. You will be asked to leave your name, address, and phone number and will need to refer to Announcement **98103**. You will receive a complete program description, information on application procedures, and application forms. CDC will not send application kits by facsimile or express mail. **PLEASE REFER TO ANNOUNCEMENT NUMBER 98103 WHEN REQUESTING**

### INFORMATION AND SUBMITTING AN APPLICATION.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained by contacting:

David Elswick, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement **98103** Centers for Disease Control and Prevention (CDC), Room 300, 255 East Paces Ferry Road, NE., M/S E-13, Atlanta, GA 30305-2209, telephone (404) 842-6521

See also the CDC home page on the Internet: <http://www.cdc.gov>.

Programmatic technical assistance may be obtained from Mark L. Messonnier, Economist, Prevention Effectiveness Branch, Division of Prevention Research and Analytic Methods, Epidemiology Program Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., Mailstop D-01, Atlanta, Georgia 30333, telephone (404) 639-4474.

Dated: July 13, 1998.

**John L. Williams,**

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

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### DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### Food and Drug Administration

[Docket No. 97E-0291]

#### Determination of Regulatory Review Period for Purposes of Patent Extension; QUADRAMET®

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for QUADRAMET® and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

**ADDRESSES:** Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration,