responsibilities that will be undertaken by the coalition members and community organizations should be included in the appendix.

5. Proposed Budget Justification (Reviewed, but not scored)

The extent to which the applicant's budget includes funds to participate in the CDC required meetings (at least one person, such as the Project Coordinator, must attend one meeting per year in Atlanta to last for two days). The applicant should provide a detailed budget request and complete line-item justification of all proposed operating expenses consistent with the stated activities under this program announcement. Applicants should be precise about the purpose of each budget item and should itemize calculations wherever appropriate. The use of budget guidance posted on the CDC website with this announcement is encouraged.

6. Measures of Effectiveness (Reviewed, but not scored)

The extent to which the applicant has provided appropriate measures of effectiveness.

7. Human Subjects (Reviewed, but not scored)

The extent to which the applicant adequately addresses the requirements of Title 45 CFR part 46 for the protection of human subjects. Not scored; however, an application can be disapproved if the research risks are sufficiently serious and protection against risks is so inadequate as to make the entire application unacceptable.

I. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of:

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. Detailed Line-Item Budget and Justification.

e. Additional Requested Information.

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. Send all reports to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

Additional Requirements

The following additional requirements are applicable to this program. For a complete description of each, see Attachment III of the program announcement, as posted on the CDC Web site.

AR–1 Human Subjects Requirements
AR–7 Executive Order 12372 Review
AR–8 Public Health System Reporting Requirements
AR–9 Paperwork Reduction Act Requirements
AR–10 Smoke-Free Workplace Requirements
AR–11 Healthy People 2010
AR–12 Lobbying Restrictions
AR–13 Prohibition on Use of CDC Funds for Certain Gun Control Activities

J. Where To Obtain Additional Information

This and other CDC announcements, the necessary applications, and associated forms can be found on the CDC web site, Internet address: *http://www.cdc.gov.* Click on ''Funding,'' then ''Grants and Cooperative Agreements''.

For general questions about this announcement, contact: Technical Information Management, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341–4146, Telephone: 770–488–2700.

For business management and budget assistance, contact: Nancy Pillar, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Room 3000, Atlanta, GA 30341–4146, Telephone number: 770–488–2721, e-mail address: *nfp6@cdc.gov.*

For program technical assistance, contact: David Wallace, MSEH, Technical Adviser, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention, 4770 Buford Highway NE, MS K–63, Atlanta, GA 30341–3724, Telephone number: 770–488–4712, e-mail address: *dwallace2@cdc.gov.*

Dated: July 2, 2003.

Edward Schultz,

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

[FR Doc. 03–18239 Filed 7–17–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 03189]

Blindness and Vision Loss Prevention Program; Notice of Availability of Funds

Application Deadline: August 18, 2003.

A. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 301 (a) and 317(k)(2) of the Public Health Service Act, 317H of the Public Health Service Act 42 U.S.C. 247 (b)(9), and section 301(a) of the Public Health Service Act, 42 U.S.C. 241(a) and 247b(k)(2), as amended. The Catalog of Federal Domestic Assistance number is 93.988.

B. Purpose

The Centers for Disease Control and Prevention (CDC), announces the availability of fiscal year (FY) 2003 funds for a cooperative agreement program for a Blindness and Vision Loss Prevention Program. This program addresses the ''Healthy People 2010'' focus area of Diabetes and Vision.

The purpose of this program is to develop, deliver, and evaluate a program of comprehensive vision screening, outreach and referral, public education, and surveillance of vision problems. This program is intended to serve persons at risk of blindness and vision loss including persons with diabetes, the elderly, racial and ethnic minorities, and children. This program is also intended to increase awareness nationwide of the need for routine eye examinations, screenings for vision loss, and the need for action to preserve and protect eyesight by developing a national model prevention program to: (a) Raise awareness of the risks of vision loss and eye disease; (b) recognize the early signs of eye disease; (c) identify appropriate and effective prevention practices; (d) implement screenings and eye examinations in target populations; (e) locate and identify where to find services for prevention, treatment, and rehabilitation; and (f) develop and maintain a national database which defines the extent of eye disease and vision loss.

Measurable outcomes of the program will be in alignment with the following performance goal for the National Center for Chronic Disease Prevention and Health Promotion: Increase the capacity of state diabetes control

programs to address the prevention of diabetes and its complications at the community level.

C. Eligible Applicants

Private, non-profit, health organizations with a national scope, that provide a comprehensive eye disease prevention program addressing diabetic retinopathy, glaucoma, cataracts, and age-related macular degeneration are eligible. The organization must provide proof of 501(c)(3) non-profit status and must have the ability to receive, manage, and account for federal funds.

Note: Public Law 104–65 states that an organization described in section 501(c)(3) of the Internal Revenue Code of 1986 which engages in lobbying activities shall not be eligible for the receipt of Federal funds constituting an award, grant, loan or any other form.

D. Funding

Availability of Funds

Approximately $875,000 is available in FY 2003 to fund one award. It is expected that the award will be made on or about September 15, 2003 and will be made for a 12-month budget period with a project period of up to five years. The Funding estimate may vary depending on availability of funds.

Continuation awards in subsequent years will be based upon the availability of funds and satisfactory progress as evidenced by required reports and achievement of the objectives set forth under ''Program Requirements''.

Use of Funds

Cooperative agreement funds may be used to expand, enhance, or complement existing activities to accomplish the objectives of this program. Funds may be used to pay for, but are not limited to, the following: staffing, consultants, contractors, grants to affiliates, materials and supplies, equipment, travel, and other associated expenses to implement and evaluate intervention activities such as screenings for vision and risk assessment for eye disease, public outreach, referrals to health professions for follow-up, public education, professional education, and the collection of representative data to define the problem and evaluate the program.

Funding under this program announcement may not be used to: (1) Support direct patient care services, individual health services, or the treatment of diabetes; (2) duplicate existing efforts the federal system has established for outpatient diabetes education reimbursement for the Medicare population through the Diabetes Education Program Recognition administered by the Centers for Medicaid and Medicare Services (CMS); or (3) supplant existing funding.

Recipient Financial Participation

Matching funds, that is, a specific percentage of program costs that must be contributed by the recipient in order to be eligible for this announcement, are not required. Applicants are encouraged, however, to identify financial and in-kind contributions from their own organizations and partners to support and sustain the activities of this program.

E. Program Requirements

The recipient funded under this program announcement will utilize, complement, and expand existing program activities and capabilities, but should not duplicate such activities. In conducting activities to achieve the purpose of this program announcement, the applicant will be responsible for the activities listed in 1. Recipient Activities, and CDC will be responsible for the activities listed in 2. CDC Activities:

1. Recipient Activities

The organization must demonstrate a national capacity through an affiliate organizational structure that has established organizational units at the state level. The organization must have demonstrated ability to acquire, implement, and manage a national database sufficient to describe the causes of blindness and vision loss.

(a) Leadership and Management

Establish and maintain an effective national leadership structure, an overall management structure that relies upon state-level affiliates to carry out the program activities, and an organization which is based upon a strategic plan. The overall management plan of the organization should include effective accountability of funds, plans for managing federal funds, and plans for disbursement of funds to affiliates. The management plan should also include strategies to collaborate with other similar national organizations and how the efforts of these other organizations will support the overall program.

(b) Screening

Build upon and expand existing screening activities to include children, the elderly, and other target populations such as racial and ethnic minorities disparately affected by vision loss. Screenings must be comprehensive, that is, you must screen for diabetic retinopathy, glaucoma, cataracts, and age-related macular degeneration. Screenings should be community-based, involve other vision partners, and should be evaluated in terms of numbers screened, findings, and referrals. (No personally identifiable data shall be collected or maintained by the recipient of this program cooperative agreement).

The screening activity must also include appropriate training and certification of the screeners to assure the highest standards of competency are provided to the public.

(c) Outreach for Treatment and Rehabilitation

Implement and/or expand the screening activity with a comprehensive referral program to assure that persons identified with vision disorders will receive appropriate referrals to professionals for necessary follow-up, care and treatment. Such a referral program should include identification of appropriate services prior to screenings, appropriate education of the screened persons (or parents or guardians) of the results of the screening, appropriate education of the screened persons (or parents or guardians) regarding the community services available, and follow-up with referral and treatment services to determine the number of persons identified as at-risk from the screenings that are taking advantage of referral services. The referral program should also determine the outcome of the referral to determine the types of treatment utilized to serve the patient. (No personally identifiable data shall be collected or maintained by the recipient of this cooperative agreement).

(d) Public Health Assessment

Conduct an assessment of the current level of programs and services provided by the public health sector to determine program areas which are complementary, or duplicative, and where gaps in services exist. Assessments should be conducted in selected States and communities to gather representative data regarding the current capacity of public health to collaborate with national vision organizations in a comprehensive blindness and vision loss prevention program. The assessments should, at a minimum, include identification of all the public health programs with an element of screening or education, the level of resources devoted, funding sources, evaluation methods (if any), responsible organizations, gaps in services, and areas for collaboration. (No more than nine states and/or

communities may receive such an assessment).

(e) Public Education

Design, expand, and implement programs to educate the public regarding the importance of periodic eye examinations, the symptoms of vision problems, the risk factors associated with vision loss, and the availability of services locally. Education campaigns should be conducted periodically targeting high-risk populations, the elderly, and other populations deemed to need the education. The messages should be designed for the target population and should be culturally relevant.

(f) Professional Education

Conduct various education campaigns designed to reach vision professionals and primary care physicians with information regarding vision loss problems, services available, professional standards and standards of care, and where to acquire additional information. Professional education campaigns may utilize Web sites, conferences, workshops, symposia, printed material, professional journals, and other appropriate literature. Professional education should also include the latest information on vision screening and diagnostic procedures as well as progress in other areas of the Blindness and Vision Loss Prevention Program.

(g) Program Evaluation and Surveillance

Describe how existing program evaluation and surveillance activities will be expanded to determine the prevalence and numbers of persons with blindness, vision loss, and other related causes. Implement or expand data collection activities to determine the numbers of people receiving appropriate eye examinations, the types of examinations, and actions taken to prevent or treat vision loss. Program evaluation and surveillance activities should not initiate new data collection but should utilize existing data sources. Program evaluation strategies should include numbers of persons reached by the program, estimated number of persons affected by blindness and vision loss, and numbers of persons with blindness and vision loss under treatment for the disease. (No personally identifiable data may be collected with these cooperative agreement funds).

Surveillance activities should identify existing data sources and how they can be utilized for the purposes of this program. Evaluation activities should include design of new program measures and future data sources, with an emphasis evaluating program performance measures consistent with long-term program objectives.

2. CDC Activities

(a) Assist as needed, in the development of a national evaluation framework that includes measurement methods, surveillance instruments for future use, data standards and definitions, and a structure for evaluating the effectiveness of program services.

(b) Provide assistance as required to develop a CDC technical advisory committee to guide program services, share information in professional settings, and ensure collaboration among relevant programs within CDC.

(c) Provide the expertise, staff, and evidence-based resources of CDC programs to assist and enhance the work of the funded organization.

(d) Support the recipient's activities by providing scientific and public health consultation and assistance in the development of activities under Recipient Activities. This includes providing technical assistance, training, and support to the funded organization in the areas of program standards, evaluation, surveillance, and service delivery through public health structures.

(e) Assist with the public health assessment in state and local health agencies to identify gaps in services and to encourage and support opportunities for collaboration and coordination.

F. Content

Letter of Intent (LOI)

A letter of intent is requested (not required) from potential applicants for the purpose of planning the competitive review of applications. The narrative should be no more than one page, single-spaced, and printed on one side. The letter of intent should identify the program announcement, the applicant organization, document proof of the applicant's non-profit status, 501(c)(3) status, and the extent to which the organization meets the eligibility requirements.

Application

The program announcement title and number must appear in the application. Utilize the information in the Program Requirements, Other Requirements, Evaluation Criteria, and this section to develop the application content. Applications will be evaluated on the criteria listed. The content requirements as well as the evaluation criteria should be followed closely. Applications should be no more than 35 pages double-spaced, printed on one side, with one-inch margins, and unreduced 12-point font. In addition to the application forms, the application must contain the following in this order:

1. *A Table of Contents with page numbers for each of the sections.*

2. *A description of the background and need for the program.*

Data that describes the problem of blindness and vision loss in the United States, as well as any social or economic data which further defines the problems should be included. Historical and other relevant information should be provided which demonstrates the applicant's understanding of the problem and how to address it. A description of the applicant organizational structure, including financial and programmatic capabilities, as well as an inventory of current organizational activities related to this announcement. The affiliate structure should also be described and how the organization achieves its mission through the affiliates. A description of the proposed staff, including attached resumes or job descriptions for a full-time project coordinator and other key staff, the qualifications and responsibilities of each staff member and the percent of time each are committing to the program should also be included.

3. *A detailed work plan for:*

(a) Screening; (b) Outreach for treatment and rehabilitation; (c) Public Health Assessment; (d) Public and Professional education; and (e) Program Evaluation and Surveillance. The work plans should be time-phased, and should include one-year and five-year program objectives including an implementation plan.

4. *A budget and budget justification.*

Provide a budget and budget justification including allocation to program areas, budgeted amounts by categories (personnel, fringe benefits, travel, equipment, supplies, contractual, and other direct costs), allocations to affiliates, and a description of the funding mechanisms and timelines that will be used to disperse funds. The budget should be detailed for one year but should include a proposed summary budget for subsequent years (four additional years). Financial contributions should be included where appropriate.

5. *Appendices.*

Supporting materials including letters of support, organizational background and history, data to describe blindness and vision loss, and strategic plans should be included in the appendices section of the application.

G. Submission and Deadline

LOI Submission

A letter of intent is requested by August 1, 2003. Submit the LOI to: Regina Hardy, Division of Diabetes Translation, CDC National Center for Chronic Disease Prevention and Health Promotion, 4770 Buford Highway, NE., Mailstop K–10, Atlanta, GA 30341.

Application Forms

Submit the signed original and two copies of the PHS 5161 Form. Forms are available at the following Internet address: *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, please contact the CDC Procurement and Grants Office Technical Information Management Section (PGO–TIM) at: 770–488–2700. Applications forms can be mailed to you.

Submission Date, Time, and Address

The application must be received by 4 p.m. Eastern Time, August 18, 2003. Submit the application to: Technical Information Management—PA 03189, CDC Procurement and Grants Office, 2920 Brandywine Rd., Atlanta, GA 30341–4146.

Applications may not be submitted electronically.

Acknowledgement of Application Receipt

A postcard will be mailed by PGO–TIM, notifying you that CDC has received your application.

Deadline

Applications shall be considered as meeting the deadline if they are received before 4 p.m. Eastern Time on the deadline date. Applications sent by the United States Postal Service or commercial delivery services must ensure that the carrier will be able to guarantee delivery of the application by the closing date and time. If an application is received 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, CDC will upon receipt of proper documentation, consider the application as having been received by the deadline. Any application that does not meet the above criteria will not be eligible for competition, and will be returned to the applicant. The applicant will be notified of their failure to meet the submission requirements.

H. Evaluation 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 goal 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.

An independent objective review group appointed by CDC will evaluate each application against the following criteria:

1. Work Plan (40 points)

The degree to which the applicant describes a plan that is time-phased, feasible and measurable. The work plan must be specific and meet the expectations in the Program Requirements and Application Content sections of this program announcement. The degree to which the plans reflect and build upon existing capabilities and assets, and utilize the capacity of the affiliates. The extent to which the plan includes efforts to sustain the program long-term. The extent to which the application describes plans to collaborate with CDC in developing an evaluation framework and performance measures. The extent to which appropriate data sources are available to define the problems of blindness and vision loss and plans to acquire additional data sources. The extent to which the application provides clear definitive plans to make the program nationwide in scope.

2. Program Leadership and Management (25 points)

The extent to which the organizational structure is designed to implement the proposed work plan including leadership and decision-making processes. The extent to which the proposed staffing will have the appropriate qualifications and experience to implement the proposed work plan. The extent to which the applicant describes clearly defined roles for program staff and the roles of the affiliates.

The extent to which the application demonstrates a capacity to guide and support their affiliates.

3. Background and Need (25 points)

The extent to which the problem of blindness and vision loss is described and supported by institutional data. The extent to which the application identifies the strengths and weakness of the current prevention programs in the United States. The extent to which the application identifies potential collaborators and the strengths they offer to the program. The extent to which the applicant has the necessary organizational capabilities to deliver the services of the program including database development and management. The extent of the applicant's ability to train and certify screeners and screening activities. The extent to which the application demonstrates a history and evidence of delivering vision loss and blindness program services.

4. Budget and Budget Narrative (10 points)

The extent to which the budget appears reasonable and consistent with the proposed activities and intent of the program.

I. Other Requirements

Technical Reporting Requirements

Provide CDC with original and two copies of:

1. Interim progress report will be due April 1, 2004 containing a brief description of the program accomplishments/narrative and progress made in the first six months of the program; reasons for not achieving proposed objectives and activities; progress in allocating and dispersing the budget; and details for changes in the program for the remainder of the time for which funds are provided.

2. An annual progress report summarizing the past year's accomplishments, and a financial status report, no more than 90 days after the end of the budget period.

3. Final financial, performance, and evaluation reports, no more than 90 days after the end of the five-year project period (depending upon availability of funds).

Send all reports to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

Additional Requirements

The following requirements are applicable to this program. For a complete description of each, *see* Attachment I of the program announcement as posted on the CDC Web site.

AR–7 Executive Order 12372 Review
AR–8 Public Health Systems Reporting Requirements
AR–10 Smoke-Free Workplace Requirements
AR–11 Healthy People 2010
AR–12 Lobbying Restrictions

J. Where To Obtain Additional Information

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

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

For business management and budget assistance, contact: Ann Gatwood, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341–4146, Telephone: 770–488–2895, E-mail address: *glg4@cdc.gov*.

For program technical assistance, contact: Jinan Saaddine, Division of Diabetes Translation, CDC National Center for Chronic Disease Prevention and Health Promotion, 4770 Buford Highway, NE., Mailstop K–10, Atlanta, GA 30341, E-mail: *JSaaddine@cdc.gov*, Telephone: (770) 488–1274.

Dated: July 14, 2003.

Sandra R. Manning,

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

[FR Doc. 03–18235 Filed 7–17–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Docket No. 2003N–0311

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Device User Fee and Modernization Act Small Business Qualification Certification (Form FDA 3602)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. The proposed collection of information will permit an applicant to certify that it qualifies as a ''small business'' within the meaning of the Medical Device User Fee and Modernization Act (MDUFMA), will help the applicant organize the information FDA needs to verify each certification, and will collect contact information to facilitate rapid resolution of any questions FDA may have concerning information the applicant has provided. In the **Federal Register** of March 26, 2003 (68 FR 14664), FDA published a notice announcing OMB's approval of this collection of information (OMB control number 0910–0508). Since this was an emergency approval that expires on October 31, 2003, FDA is following the normal PRA clearance procedures by issuing this notice.

DATES: Submit written or electronic comments on the collection of information September 16, 2003.

ADDRESSES: Submit electronic comments on the collection of information via the Internet at: *http://www.fda.gov/dockets/edockethome*. Submit written comments on the collection of information to the Divsion of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane., rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

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: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

MDUFMA Small Business Qualification Certification (Form FDA 3602) — (OMB Control Number 0910–0508)—Extension

MDUFMA amends the Federal Food, Drug, and Cosmetic Act to provide for user fees for certain medical device applications. The initial fees (for fiscal year (FY) 2003) are set by statute; FDA will publish a **Federal Register** notice by August 1, 2003, announcing the fees for FY 2004. To avoid harming small businesses, MDUFMA provides for reduced or waived fees for applicants who qualify as a ''small business.'' This means there are two levels of fees, a standard fee, and a reduced or waived small business fee.

Presently, a ''small business'' is an applicant who reported no more than $30 million ''gross receipts or sales'' on its Federal income tax return for the most recent tax year; the applicant must count the ''gross receipts or sales'' of all of its affiliates, partners, or parent firms when calculating whether it meets the $30 million threshold. An applicant must pay the full standard fee unless it provides evidence demonstrating to FDA that it meets the ''small business'' criteria. The evidence required by MDUFMA is a copy of the most recent Federal income tax return of the applicant, and any affiliate, partner, or parent firm. FDA will review these materials and decide whether an applicant is a ''small business'' within the meaning of MDUFMA.

Form FDA 3602 will be available in a forthcoming guidance document, ''MDUFMA Small Business Qualification Worksheet and Certification.'' This guidance will describe the criteria FDA will use to decide whether an entity qualifies as a MDUFMA small business and will help prospective applicants understand what they need to do to meet the small business criteria for FY 2004 and subsequent fiscal years. FDA will