AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

purpose, the Department will send correspondence requesting Phase II proposals from the Phase I grantees eligible to apply for Phase II funding in that fiscal year. The correspondence will contain information sufficient to enable eligible applicants to prepare grant proposals.

§ 3403.6 Content of proposals.

(a) The proposed research must be responsive to one of the USDA program interests stated in the research topic descriptions of the program solicitation.

(b) Proposals must cover only scientific/technological research activities. A small business concern must not propose product development, technical assistance, demonstration projects, classified research, or patent applications. Many of the research projects supported by the SBIR program lead to the development of new products based upon the research results obtained during the project. However, projects that seek funding solely for product development where no research is involved, *i.e.*, funds are needed to permit the development of a project based on previously completed research, will not be accepted. Literature surveys should be conducted prior to preparing proposals for submission and must not be proposed as a part of the SBIR Phase I or Phase II effort. Proposals principally for the development of proven concepts toward commercialization or for market research should not be submitted since such efforts are considered the responsibility of the private sector and therefore are not supported by USDA.

(c) A proposal must be limited to only one topic. The same proposal may not be submitted under more than one topic as defined in the solicitation. However, an organization may submit separate proposals on the same topic. Where similar research is discussed under more than one topic, the proposer should choose that topic whose description appears most relevant to the proposer's research concept. USDA will not consider funding duplicate (essentially equivalent work) proposals. In addition, essentially equivalent work funded by another entity will be returned to the applicant without review.

§ 3403.7 Proposal format for phase I applications.

(a) The following items relate to Phase I applications. Further instructions or descriptions for these items as well as any additional items to be included will be provided in the annual solicitation, as necessary.

(1) *SF–424 R&R Cover*. Applicants must submit basic proposal identification information on the first page of the proposals. Applicants must also certify on the first page of the proposals that they meet the definition of a small business concern as stated in the solicitation, and must certify as to whether or not they qualify as socially and economically disadvantaged small business concerns, or women-owned small business concerns.

(2) *Project Summary/Abstract*. The technical abstract should include a brief description of the problem or opportunity, project objectives, and a description of the effort. Anticipated results and potential commercial applications of the proposed research also should be summarized in the space provided. Keywords should characterize the most important aspects of the project. The project summary of successful proposals may be published by USDA and therefore should not contain proprietary information.

(3) *Project Narrative*. The main body of the proposal should include:

(i) Identification and significance of the problem or opportunity.

(ii) Background and rationale.

(iii) Relationship with future research or research and development.

(iv) Phase I technical objectives.

(v) Phase I work plan.

(vi) Related research or research and development.

(vii) References. For each reference cited in the Proposal, provide the complete name for each author, the date of publication, the full title of the article, name of the journal, etc.

(4) *Key personnel and bibliography*. Identify key personnel involved in the effort, including information on their directly related education and experience. For each key person, provide a chronological list of the most recent

representative publications in the topic area.

(5) *Facilities and equipment.* Describe the types, location, and availability of instrumentation and physical facilities necessary to carry out the work proposed. Items of equipment to be purchased must be fully justified under this section.

(6) *Outside services.* Involvement of university or other consultants in the planning and research stages of the project as consultants or through subcontracting arrangements is permitted and may be particularly helpful to small business concerns that have not previously received Federal research awards. If such involvement is intended, it should be described in detail.

(7) *Satisfying the public interest.* Specify how the proposed research will satisfy one or more of the following objectives:

(i) Develops sustainable agriculture production systems;

(ii) Protects natural resources and the environment;

(iii) Creates a safe, nutritious and affordable food supply;

(iv) Develops value-added food and non-food products from agricultural materials;

(v) Enhances global competitiveness; and

(vi) Enhances economic opportunity and quality of life, especially for people in rural areas.

(8) *Potential post applications.* Briefly describe the commercialization potential of the proposed research. Indicate whether and by what means there appears to be a potential for the Federal Government to use the proposed research. Include a brief description of the proposing company (e.g., date founded, number of employees) and its field of interest. What are the major competitive products in this field, and what advantages will the proposed research have over existing technology (in application, performance, technique, efficiency or cost)?

(9) *Similar Proposals or Awards.* (i) WARNING—While it is permissible with proposal notification to submit identical proposals containing a significant amount of essentially equivalent work for consideration under numerous Federal program solicitations, it is unlawful to enter into funding agreements requiring essentially equivalent work. If there is any question concerning this, it must be disclosed to the soliciting agency or agencies before award. If an applicant elects to submit identical proposals or proposals containing a significant amount of essentially equivalent work under other Federal program solicitations, a statement must be included in each such proposal indicating:

(A) Name and address of the agency(ies) to which the proposal was submitted, or will be submitted, or from which an award is expected or has been received.

(B) Date of actual or anticipated proposal submission or date of award, as appropriate.

(C) Title of proposal or award, identifying number assigned to the solicitation or proposal by the agency involved, and the date the proposal(s) were submitted or the award was received.

(D) Applicable research topic area for each proposal submitted or award received.

(E) Titles of research projects.

(F) Name and title of principal investigator for each proposal submitted or award received.

(ii) *USDA will not make awards that duplicate research funded (or to be funded) by other Federal agencies.*

(10) *Cost breakdown on proposal budget.* Complete a budget form for the phase under which you are currently applying. (An applicant for Phase I funding should not submit both Phase I and Phase II budgets.) A budget narrative with supporting detail for each budget category must be included.

(11) *Special Considerations.* If the proposed research will include laboratory animals or human subjects at risk, the applicant may be required to have the research plan reviewed and approved by an Institutional Animal Care and Use Committee (IACUC) or Institutional Review Board (IRB) prior to commencing actual substantive work. If such approval is required, USDA may not release funds for the award until proper documentation is submitted and accepted by USDA. It is suggested that applicants contact local universities,

colleges, or nonprofit research organizations which have established reviewing mechanisms to have this service performed.

(12) *Proprietary information.* (i) If proprietary information is provided by an applicant in a proposal which constitutes a trade secret, proprietary commercial or financial information, confidential personal information, or data affecting the national security, it will be treated in confidence to the extent permitted by law. This information must be clearly marked by the applicant with the term ''confidential proprietary information'' and the following legend must appear on the title page of the proposal: ''These data shall not be disclosed outside the Government and shall not be duplicated, used, or disclosed in whole or in part for any purpose other than evaluation of this proposal. If a funding agreement is awarded to this applicant as a result of or in connection with the submission of these data, the Government shall have the right to duplicate, use, or disclose the data to the extent provided in the funding agreement and pursuant to applicable law. This restriction does not limit the Government's right to use information contained in the data if it is obtained from another source without restriction. The data subject to this restriction are contained on pages ____ of this proposal.''

(ii) USDA, by law, is required to make the final decision as to whether the information is required to be kept in confidence. Information contained in unsuccessful proposals will remain the property of the applicant. However, USDA will retain for three years one copy of all proposals received; extra copies will be destroyed. Public release of information for any proposal submitted will be subject to existing statutory and regulatory requirements. Any proposal which is funded will be considered an integral part of the award and normally will be made available to the public upon request through the Freedom of Information Act, except for designated proprietary information.

(iii) The inclusion of proprietary information is discouraged unless it is necessary for the proper evaluation of the proposal. If proprietary information is to be included, it should be limited, set apart from other text on a separate page, and keyed to the text by numbers. It should be confined to a few critical technical items which, if disclosed, could jeopardize the obtaining of foreign or domestic patents. Trade secrets, salaries, or other information which could jeopardize commercial competitiveness should be similarly keyed and presented on a separate page. Proposals or reports which attempt to restrict dissemination of large amounts of information may be found unacceptable by USDA.

(13) *Rights in data developed under SBIR funding agreement.* The legend (or statements) in the SBIR datarights clause included in the SBIR award must be affixed to any submissions of technical data. Where such legend is affixed, rights in technical data, including software developed under the terms of any funding agreement resulting from a proposal submitted in response to the program solicitation shall remain with the grantee. The Government may not use, modify, reproduce, release, perform, display, or disclose technical data or computer software marked with this legend for 4 years. After expiration of the 4-year period, the Government has a royalty-free license to use, and to authorize others to use on its behalf, these data for Government purposes, and is relieved of all disclosure prohibitions and assumes no liability for unauthorized use of these data by third parties, except that any such data that is also protected and referenced under a subsequent SBIR award shall remain protected through the protection of that subsequent SBIR award.

(14) *Patents and Inventions.* Allocation of rights to inventions shall be in accordance with 35 U.S.C. 202 through 206 and the Department of Commerce implementing regulations entitled ''Rights to Inventions Made by Nonprofit Organizations and Small Business Firms under Government Grants, Contracts and Cooperative Agreements'' at 37 CFR part 401. These regulations provide that small businesses normally may retain the principal worldwide patent rights to any invention developed with USDA support. USDA receives a royalty-free license

for Federal Government use, reserves the right to require the patentee to license others in certain circumstances, and requires that anyone exclusively licensed to sell the invention in the United States must normally manufacture it domestically. To the extent authorized by 35 U.S.C. 205, USDA will not make public any information disclosing a USDA-supported invention for a four-year period. SBIR awardees must report inventions to the awarding agency within two months of the inventor's report to the awardee. The reporting of inventions shall be made through submission to Interagency Edison as specified in the terms and conditions of the grant.

(15) *Organizational management information.* Before the award of an SBIR funding agreement, USDA requires the submission of certain organizational management, personnel, and financial information to assure responsibility of the applicant. This information is not required unless a project is recommended for funding, and then it is submitted on a one-time basis only. However, new information should be submitted if a small business concern has undergone significant changes in organization, personnel, finance or policies, including those relating to civil rights.

(16) *Documentation of commercialization record of firms with multiple phase II awards.* A small business concern submitting a proposal for a Phase I award that has received more than 15 Phase II SBIR awards during the preceding five fiscal years must document the extent to which it was able to secure Phase III funding to develop concepts resulting from previous Phase II SBIR awards.

(b) [Reserved]

§ 3403.8 Proposal format for phase II applications.

(a) The following items relate to Phase II applications. Further instructions or descriptions for these items as well as any additional items to be included will be identified in the annual program solicitation as necessary. See § 3403.9.

(1) *SF–424 R&R cover sheet.* Follow instructions found in § 3403.7(a)(1).

(2) *Project summary.* Follow instructions found at § 3403.7(a)(2).

(3) *Phase I results.* The proposal should contain an extensive section that lists Phase I objectives and makes detailed presentation of the Phase I results. This section should establish the degree to which Phase I objectives were met and feasibility of the proposed research project was established.

(4) *Proposal.* Since Phase II is the principal research and development effort, proposals should be more comprehensive than those submitted under Phase I. However, the outline and information contained in § 3403.7(a)(3)–(9) and § 3403.7(a)(11)–(14) should be followed, tailoring the information requested to the Phase II project.

(5) *Cost breakdown on proposal budget.* For Phase II, a detailed budget is required for each year of requested support. In addition, a summary budget is required detailing the requested support for the overall project period. A budget narrative, with supporting budget detail for each budget category must be included.

(6) *Organizational management information.* Each Phase II awardee will be asked to submit an updated statement of financial condition (such as the latest audit report, financial statements or balance sheet) and report any changes in management or principals.

(7) *Commercialization Plan.* A succinct commercialization plan must be included in each SBIR Phase II proposal moving toward commercialization. Elements of a commercialization plan may include the following:

(i) *Company information.* Focused objectives/core competencies; size; specialization area(s); products with significant sales; and history of previous Federal and non-Federal funding; regulatory experience; and subsequent commercialization.

(ii) *Customer and competition.* Clear description of key technology objectives, current competition, and advantages compared to competing products or services; description of hurdles to acceptance of the innovation.

(iii) *Market.* Milestone, target dates, analyses of market size, and estimated market share after first year sales and after five years; explanation of plan to obtain market share.

(iv) *Intellectual property.* Patent status, technology lead, trade secrets or