

I. For Unintentional Injury Prevention Research

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II. For Violence Related Injury Prevention Research

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III. For Injury Related Acute Care, Disability, and Rehabilitation

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Sandra R. Manning,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement No. 02152]

Dissertation Awards for Minority Doctoral Candidates for Violence-Related Injury Prevention Research; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2002 funds for an extramural grant program for Dissertation Awards to Minority Doctoral Candidates for Violence-Related injury prevention research. This program addresses the "Healthly People 2010" focus areas of injury and violence prevention. Measurable outcomes of the program will be in alignment with one

or more of the following performance goals for The National Center for Injury Prevention and Control (NCIPC):

1. Reduce the risk of youth violence.
2. Reduce violence against women.
3. Enhance the capacity of states to implement effective rape prevention and education programs.

4. Increase external input on the research priorities, policies, and procedures related to the extramural research supported by CDC.

The purposes of this program are to:

1. Stimulate and encourage minority doctoral candidates from a variety of academic disciplines and programs, including, but not limited to public health, health care, criminal justice, and behavioral and social sciences, to conduct violence-related injury prevention research.

2. Assist minority students in the completion of their dissertation research on a violence-related topic.

3. Encourage minority investigators to build research careers related to the prevention of violence-related injuries, disabilities, and deaths.

A dissertation represents the most extensive research experience formulated and carried out by a doctoral candidate, with the advice and guidance of a mentor (the chair of the dissertation committee or other academic advisor). Dissertation research involves a major investment of the doctoral student's time, energy, and interest and its substance is often the basis for launching a research career. The number of individuals who are members of minority groups and who are engaged in violence-related injury prevention research is currently small. There is a clear need to develop new ways to assist and encourage minority researchers to become active in the conduct of studies that can advance the rapidly growing knowledge base in this field. This research initiative is aimed at providing minority students with assistance to complete their dissertation research on a violence-related topic and thereby increase their representation in violence-related injury research.

Deaths and injuries associated with interpersonal violence and suicidal behavior are a major public health problem in the United States and around the world. In 1999, over 46,000 people died from homicide and suicide in the United States. Among 15 to 24 year olds, homicide ranked as the second and the third leading causes of death. Violent deaths are the most visible consequence of violent behavior in our society. Morbidity associated with physical and emotional injuries and disabilities resulting from violence, however, also constitute an enormous

public health problem. For every homicide that occurs each year there are over 100 non-fatal injuries resulting from interpersonal violence. For every completed suicide it is estimated that there are 20 to 25 suicide attempts. The mortality and morbidity associated with violence are associated with a variety of types of violence including child maltreatment, youth violence, intimate partner violence, sexual violence, elder abuse, and self-directed violence or suicidal behavior. Violence has a disproportionate impact on racial and ethnic minorities. In 1999, homicide was the leading cause of death for African Americans and the second leading cause of death for Hispanics between the ages of 15 and 34. Suicide was the second leading cause of death for American Indians and Alaskan Natives and Asian and Pacific islanders 15 to 34 years of age. It is important to note that existing research indicates that race or ethnicity, per se, is not a risk factor for violent victimization or a cause of violent behavior. Rather, racial or ethnic status is associated with many other factors, such as poverty, that do influence the risk of becoming a victim or behaving violently. Nevertheless, racial and ethnic minorities in the United States are at high risk for both violent victimization and perpetration. A better understanding of the factors that contribute to this vulnerability or protection from such risk is important to furthering effective violence prevention programs that address racial and ethnic minorities.

There is a critical need for highly qualified scientists to carry out research on violence that can help in the development, implementation, and evaluation of effective violence prevention programs. In particular, scientists are needed that bring an understanding and sensitivity to the problems of violence as they affect minority communities. The primary purpose of this extramural research grant program is to attract young minority scientists to the field of violence by encouraging doctoral candidates from a variety of disciplines to conduct violence prevention research and hopefully carry this focus on throughout their careers.

B. Eligibility

Eligible Institutions

Eligible institutions include any United States public or private institution such as a university or college that supports an accredited doctoral level training program. The performance site must be domestic.

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.

Eligible Applicants

Applicants must be minority students in good standing enrolled in an accredited doctoral degree program. Applicants must have also successfully defended their dissertation proposal to be eligible for this funding. For the purpose of this program announcement, minorities are defined as individuals belonging to a particular ethnic or racial group (as defined by the U.S. Census Bureau) that has been determined by the applicant institution to be under-represented in biomedical or behavioral research. Applicants must be conducting or intending to conduct research in one of the areas described under the Research Objectives section. The applicant must have obtained approval of the dissertation proposal by the dissertation committee by the time of application. The applicant's eligibility must be verified in a letter of certification from the mentor (the chair of the dissertation committee or other academic advisor) and submitted with the grant application.

The following are applicant requirements:

1. The principal investigator must be a full-time doctoral student in an accredited doctoral program. The principal investigator must have the authority and responsibility to carry out the proposed project.
2. The application must propose dissertation research that will help expand and advance our understanding of violence, its causes, and prevention strategies.
3. The applicant must have the ability to carry out an injury prevention research project with the advice of and consultation of a senior research mentor.
4. The overall match between the applicant's proposed topic and research objectives, and the research objectives described under the Program Requirements.

C. Availability of Funds

Approximately \$100,000 is expected to be available in FY 2002 for up to five dissertation awards for minority doctoral candidates. The availability of Federal funding may vary and is subject to change. It is expected that the awards will begin on or about September 30, 2002, and will be made for a 12-month budget period within a one-year project period. Applications that exceed the

funding caps noted above will be excluded from the competition and returned to the applicant.

Grants to support dissertation research will provide no more than \$20,000 in direct and indirect costs. An application that exceeds this limit will be returned to the applicant without review. Grants will be awarded for twelve months, but may be extended without additional funds for up to a total of 24 months. Grant funds will not be made available to support the provision of direct patient care including medical and/or psychiatric care.

Allowable costs include direct research project expenses, such as interviewer expenses, data processing, participant incentives, statistical consultant services, supplies, and dissertation printing costs; and travel to one scientific meeting, if adequately justified. Applicants should include travel costs for one two-day trip to CDC in Atlanta to present research findings. No tuition support is allowed.

D. Program Requirements

Research Objectives

For the purpose of this program announcement the highest priority will be given to dissertation research that addresses the following areas of inquiry:

- a. Identifying shared and unique risk and protective factors for the perpetration of intimate partner violence, sexual violence, child maltreatment, youth violence, or suicidal behaviors, and examining the relationships among these forms of violence.
- b. Evaluating the efficacy and effectiveness of interventions, programs, and policies to prevent intimate partner violence, sexual violence (includes both sexual violence against adults and child sexual abuse), child maltreatment, youth violence, or suicidal behavior.
- c. Evaluating strategies for disseminating and implementing evidence-based interventions or policies for the prevention of intimate partner violence, sexual violence, child maltreatment, youth violence, or suicidal behavior.

Other Special Conditions for Dissertation Research Grants

- a. The doctoral candidate must be the designated principal investigator. The principal investigator will be responsible for planning, directing, and executing the proposed project with the advice and consultation of the mentor and dissertation committee.
- b. The responsible program official for CDC must be informed if there is a

change of mentor. A biographical sketch of the new mentor must be provided for approval by the CDC program official.

c. A dissertation research grant may not be transferred to another institution, except under unusual and compelling circumstances (such as if the mentor moves to a new institution and both the mentor and the applicant wish to move together).

d. Two copies of the dissertation, including abstract, must be submitted to the CDC program official and will constitute the final report of the grant. The dissertation must be officially accepted by the dissertation committee or university official responsible for the candidate's dissertation and must be signed by the responsible university official.

e. Any publications directly resulting from the grant should be reported to the CDC program official. The grantee also should cite receiving support from the NCIPC and CDC, both in the dissertation and any publications directly resulting from the dissertation grant.

E. Content

Letter of Intent (LOI)

A LOI is optional for this program. The narrative should be no more than two double-spaced pages, printed on one side, with one-inch margins, and unredacted font. The letter should identify the announcement number, the name of the principal investigator, and briefly describe the scope and intent of the proposed research work. The letter of intent does not influence review or funding decisions, but the number of letters received will enable CDC to plan the review more effectively and efficiently.

Application

Use the information in the Program Requirements and Evaluation Criteria sections described below 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.

Application forms must be submitted in the following order:

Cover letter
Table of Contents
Application
Budget Information Form
Budget Justification
Checklist
Assurances
Certifications
Disclosure Forms
HIV Assurance Form (If Applicable)
Human Subjects Certification
Indirect Cost Rate Agreement
Narrative

Applications should follow the PHS-398 (Rev. 5/2001) application and Errata sheet and should include the following information:

1. The project's focus that justifies the research needs and describes the scientific basis for the research, the expected outcome, and the relevance of the findings to reduce injury morbidity, mortality, and economic losses.

2. Specific, and time-framed objectives.

3. A detailed plan describing the methods by which the objectives will be achieved, including their sequence.

4. A description of the principal investigator's role and responsibilities, along with that of the mentor.

5. A description of all project staff regardless of their funding source. It should include their title, qualifications, experience, percentage of time each will devote to the project, as well as that portion of their salary to be paid by the grant.

6. A description of those activities related to, but not supported by the grant.

7. A description of the involvement of other entities that will relate to the proposed project, if applicable. Letters of collaboration and a clear statement of their roles are required from all collaborating organizations.

8. A detailed budget for the grant.

9. An explanation of how the research findings will contribute to the national effort to reduce the morbidity, mortality and disability caused by violence-related injuries.

The narrative portion of the application that describes the Research Plan for the dissertation may not exceed fifteen pages.

Additional Materials Required

The applicant must also submit the following materials, attached to the application as appendices:

1. A letter from the applicant's mentor which: (a) Fully identifies the members of the dissertation committee and certifies their approval of the dissertation proposal. (b) Certifies that the mentor has read the application and believes that it reflects the work to be completed in the dissertation. (c) Certifies that the institution's facilities and general environment are adequate to conduct the proposed research.

2. A tentative time line for completion of the research, the dissertation, and the dissertation defense.

3. An official transcript of the applicant's graduate school record showing that the applicant has completed all required coursework for the degree with the exception of the dissertation.

4. A statement of the applicant's career goals and intended career trajectory.

5. A biography of the mentor, limited to two pages (use the Biographical Sketch page in application form PHS 398).

F. Submission and Deadline

Letter of Intent (LOI)

On or before June 1, 2002, submit the LOI to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

Application

Submit the original and five copies of PHS 398 (OMB Number 0925-0001) (adhere to the instructions on the Errata Instruction sheet for PHS 398). Forms are in the application kit and at the following Internet address: www.cdc.gov/od/pgo/forminfo.htm.

On or before 5 pm Eastern Time on June 14, 2002, submit the application to the Technical Information Management Section: 2920 Brandywine Road, Suite, 3000, Atlanta, Georgia 30341.

Deadline

Applications shall be considered as meeting the deadline if they are received before 5 pm Eastern Time on the deadline date. Applicants sending applications 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.

Applications that do not meet the above criteria will not be eligible for competition and will be discarded. Applicants will be notified of their failure to meet the submission requirements.

G. Evaluation Criteria

Upon receipt, applications will be reviewed by CDC staff for completeness, responsiveness and eligibility as outlined under the Eligible Applicants Section. Incomplete applications, that are not responsive, or applications from applicants that are not eligible will be returned to the applicant without further consideration. It is especially important that the applicant's abstract reflects the project's focus, because the

abstract will be used to help determine the responsiveness of the application.

Applications which are complete and responsive may be subjected to a preliminary evaluation (triage) by a peer review committee, the Injury Research Grant Review Committee (IRGRC) to determine if the application is of sufficient technical and scientific merit to warrant further review by the IRGRC; CDC will withdraw from further consideration applications judged to be noncompetitive and promptly notify the principal investigator and the official signing for the applicant organization. Those applications judged to be competitive will be initially reviewed by the IRGRC and the secondary review will be conducted by the Science and Program Review Subcommittee (SPRS) of the Advisory Committee for Injury Prevention and Control (ACIPC).

Awards will be determined by the Director of the NCIPC based on priority scores assigned to applications by the primary review committee (IRGRC), recommendations by the secondary review committee, e.g., the ACIPC, consultation with NCIPC senior staff, and the availability of funds.

1. The primary review will be a peer review conducted by the IRGRC. A committee of no less than three reviewers will review all applications for scientific merit with appropriate expertise using current National Institutes of Health (NIH) criteria to evaluate the methods and scientific quality of the application. Factors to be considered will include:

- a. Significance: Does this study address an important problem?

- b. Approach: Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project?

- c. Innovation: Does the project employ novel concepts, approaches or methods? Are the aims original and innovative? Does the project challenge or advance existing paradigms, or develop new methodologies or technologies?

- d. Investigator: Is the principal investigator appropriately trained and well suited to carry out this work? Is the proposed work appropriate to the experience level of the principal investigator? Is the name and role of a scientific mentor described?

- e. Environment: Does the scientific environment in which the work will be done contribute to the probability of success? Is there evidence of agreements to collaborate or other institutional support?

- f. Ethical Issues: What provisions have been made for the protection of

human subjects and the safety of the research environments? Where relevant, how does the applicant plan to handle issues of confidentiality and compliance with mandated reporting requirements, e.g., suspected child abuse? Does the application adequately address the requirements of 45 CFR part 46 for the protection of human subjects? (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.) The degree to which the applicant has met the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research. This includes:

(1) The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation.

(2) The proposed justification when representation is limited or absent.

(3) A statement as to whether the design of the study is adequate to measure differences when warranted.

(4) 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.

g. Study Samples: Are the samples rigorously defined to permit complete independent replication at another site? Have the referral sources been described, including the definitions and criteria? What plans have been made to include women and minorities, and their subgroups as appropriate for the scientific goals of the research? How will the applicant deal with recruitment and retention of subjects?

h. Dissemination: What plans have been articulated for disseminating findings?

The IRGRC will also examine the appropriateness of the proposed project budget and duration in relation to the proposed research and the availability of data required for the project.

2. The secondary review will be conducted by the SPRS of the ACIPC. The ACIPC Federal ex officio members will be invited to attend the secondary review, will receive modified briefing books, (i.e., abstracts, strengths and weaknesses from summary statements, and project officer's briefing materials). The NCIPC Division Associate Directors for Science (ADS) or their designees will attend the secondary review in a similar capacity as the Federal ex officio members. Only SPRS members will vote on funding recommendations, and their recommendations will be carried to the entire ACIPC for voting by the ACIPC

members in closed session. If any further review is needed by the ACIPC, regarding the recommendations of the SPRS, the factors considered will be the same as the factors that the SPRS considered.

The Secondary Review Committee's responsibility is to develop funding recommendations for the NCIPC Director based on the results of the primary review and the relevance and balance of proposed research relative to the NCIPC programs and priorities. The Committee has the latitude to recommend to the NCIPC Director, to reach over better ranked proposals in order to assure maximal impact and balance of proposed research.

The factors to be considered will include:

A. The results of the primary review including the application's priority score as the primary factor in the selection process.

B. The relevance and balance of proposed research relative to the NCIPC programs and priorities.

C. The significance of the proposed activities in relation to the priorities and objectives stated in "People 2010" and the Institute of Medicine report, "Reducing the Burden of Injury."

D. Budgetary considerations.

H. Other Requirements

Technical Reporting Requirements

The grantee must provide CDC with an original plus two copies of:

1. The dissertation, including abstract that will constitute the final report of the grant.

2. A financial status report, no more than 90 days after the end of the budget period.

3. At the completion of the project, the grant recipient will submit a brief (2,500 to 4,000 words written in non-scientific [laymen's] terms) summary highlighting the findings and their implications for injury prevention programs, policies, environmental changes, etc. The grant recipient will also include a description of the dissemination plan for research findings. This plan will include, publications in peer-reviewed journals and ways in which research findings will be made available to stakeholders outside of academia, (e.g., state injury prevention program staff, community groups, public health injury prevention practitioners, and others). CDC will place the dissertation abstract with the National Technical Information Service (NTIS) to further the agency's efforts to make the information more available and accessible to the public.

Send all reports to the Grants Management Specialist identified in the

"Where to Obtain Additional Information" section of this announcement.

The following additional requirements are applicable to this program.

- AR-1 Human Subjects Certification
- AR-2 Requirements for inclusion of Women and Racial and Ethnic Minorities in Research
- AR-3 Animal Subjects Requirement
- AR-9 Paperwork Reduction Requirements
- AR-10 Smoke-Free Workplace Requirement
- AR-11 Healthy People 2010
- AR-12 Lobbying Restrictions
- AR-13 Prohibition on Use of CDC funds for Certain Gun Control Activities
- AR-21 Small, Minority, and Women-owned Business
- AR-22 Research Integrity

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 301(a) (42 U.S.C. 241(a)) of the Public Health Service Act and section 391(a) (42 U.S.C. 280(b)) of the Public Service Health Act, as amended. The catalog of Federal Domestic Assistance number is 93.136.

J. Where To Obtain Additional Information

This and other CDC announcements, the necessary application and associated forms can be found on the CDC homepage Internet address—<http://www.cdc.gov>. Click on "Funding" then "Grants and Cooperative Agreements."

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Nancy Pillar, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Program Announcement 02152, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Atlanta, Georgia 30341. Telephone: (770) 488-2721. Email address: nfp6@cdc.gov.

For program technical assistance, contact: Melinda Williams, Project Officer, Prevention Development and Evaluation Branch, Division of Violence Prevention, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE, Mail Stop K-60, Atlanta, GA 30341-4723. Telephone: (770) 488-4647. Email address: mwilliams1@cdc.gov.

Dated: May 3, 2002.

Sandra R. Manning,

*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. 02N-0144]

Bavarian Red Cross; Opportunity for Hearing on a Proposal to Revoke U.S. License No. 1002

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for a hearing on a proposal to revoke the biologics license (U.S. License No. 1002), issued to the Bavarian Red Cross (BRC), for the manufacture of Whole Blood and Red Blood Cells. The proposed revocation is based on the failure of the establishment and the product for which the license has been issued, to conform to the applicable standards established in the license and in the regulations.

DATES: The firm may submit written or electronic requests for a hearing by June 10, 2002, and any data and information justifying a hearing by July 8, 2002. Other interested persons may submit written or electronic comments on the proposed revocation by July 8, 2002.

ADDRESSES: Submit written requests for a hearing, any data and information justifying a hearing, and any written comments on the proposed revocation to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to: <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT:

Michael D. Anderson, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION: FDA is initiating proceedings to revoke the biologics license (U.S. License No. 1002) issued to BRC, Herzog-Heinrich-Strasse 4, D-80336, Munich, Germany, for the manufacture of Whole Blood and Red Blood Cells. Additional locations affected by the proposed revocation include: Prof.-Ernst-Nathan-Str. 1, D-

90419, Nurnburg, Germany; Klinikstrasse 5, D-97070, Wurzburg, Germany; Dr. Franz-Strasse 3, D-95445, Bayreuth, Germany; Westheimer Strasse 80, D-86156, Augsburg, Germany; Nikolaus-Fey-Strasse 32, D-97353, Wiesentheid, Germany; and Hoher Kreuz Weg 7, D-93055, Regensburg, Germany. The proposed revocation is based on the failure of BRC to conform to the applicable standards established in its license and the requirements of parts 211 and 600 to 680 (21 CFR parts 211 and 600 to 680).

FDA inspected four of the six licensed locations of the BRC from October 27 through November 13, 1997. The inspections were conducted at the Munich, Wiesentheid, Nurnberg, and Bayreuth facilities. During the inspections, FDA observed significant deviations from the standards established in the license as well as the applicable Federal regulations. The standards and regulations are designed to ensure the continued safety, purity, and potency of the manufactured product. FDA also determined that the firm had discontinued the manufacture of Whole Blood and Red Blood Cells intended for distribution in the United States. FDA concluded that a meaningful inspection of BRC's ability to appropriately manufacture products under the license could not be made. The deviations noted during the inspections included, but were not limited to, the following: (1) In violation of § 640.3(b), donor suitability was not adequately determined, in that questions were not asked, concurrently with the direct questions on high risk behavior, for exclusion of donors who are at increased risk for human immunodeficiency virus-1 (HIV-1) group O infection; (2) in violation of §§ 606.140, 610.40, and 610.45, inspections of the Nurnburg and Munich facilities disclosed that the Abbott Prism system, a device not approved by FDA, was utilized to test for antibody to HIV types 1 and 2 plus O (anti-HIV \pm), the hepatitis B surface antigen (HBsAg), the antibody to hepatitis B core antigen (anti-HBc), and antibody to hepatitis C virus encoded antigen (anti-HCV). Additionally, blood and blood products were not tested for HIV-1 antigen and antibody to human lymphotropic virus type I (anti-HTLV-I); (3) in violation of § 606.140, the New LAV-Bolt I by Sanofi Diagnostics Pasteur, an HIV-1 western blot assay that was not approved by FDA, was used as an assay for reentry of donors; (4) in violation of § 606.140, the New LAV-Bolt II by Sanofi Diagnostics Pasteur, an HIV-2 western blot assay

that was not approved by FDA, was used as an assay for reentry of donors; and (5) in violation of § 606.121(c)(5)(i), blood and blood products that were intended for transfusion and collected from paid donors were not labeled as to distinguish them from blood products collected from volunteer donors.

In a letter dated July 8, 1998, and issued under § 601.5(b), FDA outlined the deviations noted at the inspection. FDA notified BRC of FDA's intent to revoke U.S. License No. 1002 and announced its intent to offer an opportunity for a hearing unless the deviations were adequately addressed. In a letter to FDA dated July 30, 1998, BRC responded to FDA's concerns about the inability to inspect products prepared under the U.S. License No. 1002.

In a certified, return-receipt letter to BRC, dated January 21, 1999, FDA stated that the firm's July 30, 1998, response was inadequate to address all the violations that FDA documented at the inspections. FDA advised BRC that its response was unsatisfactory in that BRC had not provided a comprehensive corrective action plan, adequate to bring the firm into compliance with the applicable Federal standards and regulations. In the same letter, FDA suggested that the firm voluntarily request that U.S. License No. 1002 be revoked, and a new application be submitted at a later date.

In a letter dated November 3, 2000, FDA notified BRC that since the receipt of the July 30, 1998, letter to FDA, FDA had not received any additional response from the firm. The letter stated that under § 601.5(b)(2), FDA had provided a reasonable period for the firm to demonstrate or achieve compliance with the applicable standards established in the license and regulations before proceeding to initiate revocation of U.S. License No. 1002. Since BRC did not submit a response addressing the methods intended to demonstrate or achieve compliance and did not waive an opportunity for a hearing, FDA notified the firm in the same letter of FDA's intent to revoke the license and to issue a notice of opportunity for a hearing under § 12.21(b) (21 CFR 12.21(b)).

Under § 12.21(b), FDA is issuing a notice of opportunity for a hearing on a proposal to revoke the biologics license (U.S. License No. 1002) issued to BRC.

FDA has placed copies of the documents relevant to the proposed revocation on file with Dockets Management Branch (see **ADDRESSES**) under the docket number found in brackets in the heading of this document. These documents include: