Budget and Cost-Effectiveness (Not Scored)

Creative and convincing approaches to resource utilization (financial, personnel, computing, *etc.*) to lead to a major impact of available resources.

Human Subjects (Not Scored)

The extent to which the application adequately addresses the requirements listed in the 45 CFR part 46 for the protection of human subjects.

H. Other Requirements

Technical Reporting Requirements

1. Provide CDC with original plus two copies of the quarterly progress reports.

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

3. Final financial report and performance report, no more than 90 days after the end of the project period

4. Measures of effectiveness that will demonstrate the accomplishment of the various identified objectives of the grant/cooperative agreement. Measures must be objective/quantitative and must measure the intended outcome. These Measures of Effectiveness shall be submitted with your application and shall be an element of evaluation.

Obtain annual audit of these CDC funds (program-specific audit) by a U.S.-based audit firm with international branches and current licensure/authority in country and in accordance with International Accounting Standards or equivalent standard(s) approved in writing by CDC.

A fiscal Recipient Capability Assessment may be required with the potential awardee, prior or post award, in order to review their business management and fiscal capabilities regarding the handling of U.S. Federal funds.

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. For a complete description of each, *see* Attachment I of the announcement.

—1AR–1 Human Subjects Requirements
—1AR–2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
—1AR–4 HIV/AIDS Confidentiality Provisions
—1AR–12 Lobbying Restrictions
—1AR–14 Accounting System Requirements
—1AR–15 Proof of Non-Profit Status
—1AR–22 Research Integrity

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 307 of the Public Health Service Act, (42 U.S.C. 2421), as amended. The Catalog of Federal Domestic Assistance number is 93.118.

J. Where to Obtain Additional Information

This and other CDC announcements can be found on the CDC home page Internet address—*http://www.cdc.gov*. Click on ''Funding'' then ''Grants and Cooperative Agreements.''

To receive additional written information and to request an application kit, call 1–888–GRANTS4 (1–888–472–6874). You will be asked to leave your name and address and will be instructed to identify the Program Announcement number of interest.

To obtain business management technical assistance, contact: Dorimar Rosado, Grants Management Specialist, Grants Management Branch, Procurement & Grants Office, Centers for Disease Control and Prevention, Room 3000, 2920 Brandywine Road, Atlanta, GA 30341–4146. Telephone: (770) 488–2782. E-mail: *dpr7@cdc.gov*.

For program technical assistance, contact: Mark D. Fussell, Global AIDS Program (GAP), Zimbabwe Country Team, National Center for HIV, STD, and TB Prevention, Centers for Disease Control and Prevention (CDC), Zim-CDC AIDS Project Team, 38 Samora Machel Avenue, 2nd Floor, Harare, Zimbabwe. Telephone: 263 4 796040, 796048. Fax: 263 4 796032. E-mail: *fussellm@zimcdc.co.zw*.

Dated: May 17, 2002.

Edward Schultz,

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

[FR Doc. 02–12931 Filed 5–22–02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 02060]

National Cancer Prevention and Control Program: Notice of Availability of Funds; Amendment

A notice announcing the availability of Fiscal Year 2002 funds for cooperative agreements for the National Cancer Prevention and Control Program was published in the **Federal Register** on April 23, 2002, (67 FR 19932). The notice is amended as follows:

Page 19933, Column 1, Paragraph ''C. Availability of Funds,'' the following clarification is added: ''Note: Awards under this program announcement will be on or about September 30, 2002 and will be made for a nine-month budget period for the first year which will end on June 29, 2003. As a result, the budget for the first year will reflect work for nine months, and subsequent years budgets will be for 12 months. As programs are funded on an annual basis, grantees under NCCCP and NBCCEDP may consider requesting additional funds in an amount equivalent to a 12-month award. The itemized budget for the first year must include a description and justification for the request. Breast and Cervical Cancer Programs are cautioned that the request must comply with the 60/40 distribution required under the program. This statement does not apply to NPCR programs since 3 month cost extensions under current grants for the period July 1, 2002 through September 29, 2002 were already funded with current year funding.''

Page 19933, Column 1, continuation of ''Eligible Applicants'' Section ''B.2.a NCCP'' is amended to read: ''Federally recognized Indian Tribal governments and Tribal organizations, urban Indian organizations and inter-tribal consortia (hereafter referred to as Tribes) whose primary purpose is to improve American Indian/Alaska Native health and which represent the Native population in their catchment area.''

Page 19939, Column 2, Section ''H.2. Availability of Funds'' is amended to add: ''Pending availability of funds, each year of the project period for this overall program announcement (September 30, 2002 to June 29, 2007) will incorporate an open season for competitive applications for the NBCCEDP component with applications due on or about February 28th. (Specific guidance with exact dates, will be provided in future years.) At that time, eligible applicants may apply.''

Page 19940, Columns 2 and 3, under Section ''H.3.a. Recipient Activities'' is amended to add: Section H.3a(6) ''If funded to provide WISEWOMAN services to NBCCEDP clients, work collaboratively across programs to ensure that each program is maximally effective and supportive of the other.''

Page 19943, Column 1, Section ''H.4.a.(8)(k), paragraph 2'', is amended to read: In addition, programs must provide the CPT codes and schedule of fees for breast and cervical cancer screening and diagnostic services to be used by the program. In States/Tribes/

Territories where there are multiple Medicare rates and a single reimbursement rate is proposed, the applicant must provide justification for approval.''

Page 19943, Column 3, Section I.2. Availability of Funds is amended to add: ''Pending availability of funds, each year of the project period for this overall program announcement (September, 30, 2002 to June 29, 2007) will incorporate an open season for competitive applications for the NPCR component with applications due on or about February 28th. (Specific guidance with exact dates will be provided in future years.) At that time, eligible applicants may apply for Part I Enhancement or Part II Planning dollars but not both.''

Page 19945, Column 1, continuation of Section I.3.a.(2) (1st sentence) is amended to read: ''published in ''Standards for Cancer Registries'', Volume II, North American Association of Central Cancer Registries (NAACCR), Spring 2002 (NAACCR record layout version 9.1).''

Page 19947, Column 2, Section ''I.4.a.(7) Operational Plan'' is deleted. Clarification added: ''Applications should address Section I.4.a.(9) Workplan.''

Page 19947, Column 3, Section I.4.a(9)(g) is deleted. Clarification added: ''Applications should address Section I.4.a.(5) Management and Staffing Plan.''

Page 19949, Column 3, Section J.2.(a) is amended to add: AAR–8''.

Page 19949, Column 3, Section J.2.(b) is amended to delete: AAR–2''.

Page 19949, Column 3, Section J.2.(c) is amended to delete: AAR–2''.

The following clarification is for information that appeared only on the CDC website. See www.cdc.gov ''Funding Opportunities.''

Attachment D—Screening Projections Matrix in the Appendices

The title of the second matrix is amended to read: ''Number of Women to be Screened in FY 2002–2003 by Characteristics.''

Dated: May 17, 2002.

Edward Schultz,

Acting 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. 01P–0447]

Determination That Ardeparin Sodium Injection Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that ardeparin sodium injection (Normiflo) was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for ardeparin sodium injection.

FOR FURTHER INFORMATION CONTACT: David Read, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5605.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved under a new drug application (NDA). Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products with Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

Ardeparin sodium injection (Normiflo) was the subject of approved NDA 20–227, formerly held by Wyeth-Ayerst and then by Pharmacia & Upjohn. Normiflo is a low molecular weight heparin indicated for the prevention of deep vein thrombosis which may lead to pulmonary embolism following knee replacement surgery. FDA received a request from Pharmacia & Upjohn, dated May 22, 2001, to withdraw approval of NDA 20–227 for Normiflo injection in accordance with 21 CFR 314.150(c). Following Pharmacia & Upjohn's request, Normiflo was moved from the prescription drug product list to the ''Discontinued Drug Product List'' section of the Orange Book. Approval of the application was withdrawn on February 11, 2002 (67 FR 6264).

In a citizen petition dated September 19, 2001 (Docket No. 01P–0447/CP1), submitted under 21 CFR 10.30, John W. Herr requested that the agency determine whether ardeparin sodium injection was withdrawn from sale for reasons of safety or effectiveness.

The agency has determined that Normiflo was not withdrawn from sale for reasons of safety or effectiveness. The petitioner identified no data or other information suggesting that Normiflo was withdrawn from sale as a result of safety or effectiveness concerns. FDA has independently evaluated relevant literature and data for possible postmarketing adverse event reports, but has found no information that would indicate this product was withdrawn for reasons of safety or effectiveness.

After considering the citizen petition and reviewing its records, FDA determines that, for the reasons outlined in this notice, ardeparin sodium injection approved under NDA 20–227 was not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list Normiflo (ardeparin sodium injection) in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to Normiflo (ardeparin sodium