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.

[FR Doc. 02–12933 Filed 5–22–02; 8:45 am]

BILLING CODE 4163–18–P

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Determination That Ardeparin Sodium Injection Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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SUMMARY: The Food and Drug Administration (FDA) has determined that ardeparin sodium injection (Normiflo) was not withdrawn from sale for reasons of safety or effectiveness.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

injection) may be approved by the agency.

Dated: May 15, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–12874 Filed 5–22–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1563]

Guidance for Industry on Carcinogenicity Study Protocol Submissions; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Carcinogenicity Study Protocol Submissions.'' This document is intended to provide guidance on the types of information the Center for Drug Evaluation and Research (CDER) relies on when evaluating protocols for animal carcinogenicity studies.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance 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. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Robert E. Osterberg, Center for Drug Evaluation and Research (HFD–24), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5476.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Carcinogenicity Study Protocol Submissions.'' In conjunction with the reauthorization of the Prescription Drug User Fee Act of 1992 (PDUFA), FDA agreed to specific performance goals (PDUFA goals) for activities associated with the development and review of products in human drug applications. The PDUFA goals related to special protocol assessment and agreement provide that, upon request, FDA will evaluate within 45 calendar days certain protocols and issues relating to the protocols to assess whether they are adequate to meet scientific and regulatory requirements identified by the sponsor. Protocols for animal carcinogenicity studies are eligible for this special protocol assessment. This guidance is intended to facilitate the agency's review of protocols for animal carcinogenicity studies by informing sponsors of the types of information the agency relies on during its evaluation of such protocols. A draft guidance of the same name was made available for public comment in a notice published in the **Federal Register** of November 7, 2000 (65 FR 66757). This guidance contains only minor changes for clarification.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on carcinogenicity study protocol submissions. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may, at any time, submit written or electronic comments on the guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: May 15, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–12872 Filed 5–22–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Availability of Funds

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: General Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) announces that applications will be accepted for fiscal year 2002 competitive Cooperative Agreements for health workforce research.

Purpose

The purpose of these Cooperative Agreements is to conduct research that will contribute to: (1) The development of information describing the current status of the health professions workforce and (2) the analysis of fundamental health workforce related issues. These Cooperative Agreements will support a wide range of projects designed to address health workforce issues at the National, Regional and State levels.

Authorizing Legislation

These Cooperative Agreements are governed by section 761 of Title VII of the Public Health Service Act, as amended, which authorizes the development of information describing the health professions workforce and analysis of workforce related issues and necessary information for decision-making regarding future direction in health professions and nursing programs in response to societal and professional needs. Section 761 also authorizes the development of a non-Federal analytic and research infrastructure for health workforce data collection and analysis.

Federal Role

The Federal role in the conduct of these cooperative agreements allow for substantial Federal programmatic involvement in the planning and development of and the reports resulting from these studies. The Bureau of Health Professions (BHPr) program officer may be assisted in this effort by program staff of the BHPr divisions. The Federal Government involvement will include: