the **Federal Register** of March 7, 2003 (68 FR 11120). The agency is taking this action in response to informal requests for an extension of the comment period.

DATES: Submit written or electronic comments on the concept papers by May 30, 2003.

ADDRESSES: Submit written requests for single copies of the concept paper(s) to Lee Lemley, Executive Operations Staff (HFD–006), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the concept papers.

Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, e-mail: *FDADockets@oc.fda.gov*, or on the Internet at *http://accessdata.fda.gov/scripts/oc/dockets/commentdocket.cfm*.

FOR FURTHER INFORMATION CONTACT: Lee Lemley, Center for Drug Evaluation and Research (HFD–006), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–6218, *lemleyl@cder.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 7, 2003 (68 FR 11120), FDA published a document announcing a public workshop to discuss risk management activities for drug and biological products (excluding blood products other than plasma derivatives). The public workshop was held, as scheduled, on April 9, 10, and 11, 2003. To facilitate public input and discussion, FDA simultaneously had issued three concept papers for review and comment entitled: (1) ''Premarketing Risk Assessment,'' (2) ''Risk Management Programs,'' and (3) ''Risk Assessment of Observational Data: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment.'' Interested persons were given until April 30, 2003, to submit written or electronic comments on the concept papers. In response to informal requests from interested persons for additional time to submit comments on the concept papers, FDA has decided to reopen the comment period until May 30, 2003.

II. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the concept papers. You should annotate and organize your comments to identify the specific concept paper and issue to which the comments refer. Where possible, comments should reference line numbers in the concept papers. Two paper copies of any mailed comments are to be submitted, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The concept papers and received comments may be seen at the Dockets Management Branch between 9 a.m. and 4 p.m. Monday through Friday.

III. Electronic Access

Electronic versions of the concept papers are available via the Internet at *http://www.fda.gov/cder/meeting/riskmanagement.htm*.

Dated: May 2, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–11497 Filed 5–8–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Science Advisory Board to the National Center for Toxicological Research; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Science Advisory Board (SAB) to the National Center for Toxicological Research (NCTR).

General Function of the Committee: The Board advises the Director, NCTR, in establishing, implementing, and evaluating the research programs that assist the Commissioner of Food and Drugs in fulfilling his regulatory responsibilities. The Board provides an extra-agency review in ensuring that the research programs at NCTR are scientifically sound and pertinent.

Date and Time: The meeting will be held on June 19, 2003, from 9 a.m. to 4:45 p.m. and on June 20, 2003, from 9 a.m. to 12:15 p.m.

Location: NCTR, Building #12, Conference Center, 3900 NCTR Dr., Jefferson, AR 72079.

Contact Person: Leonard M. Schechtman, NCTR (HFT–10), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6696, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12559. Please call the Information Line for up-to-date information on this meeting.

Agenda: The Board will be presented with a draft report on the evaluation of the Division of Biometry. The draft report is the product of a site visit team that conducted an onsite review of the Division in May. Division staffers will provide a preliminary response to the issues raised and recommendations made.

The establishment of a Pharmaceutical Safety Working Group and the background and history of two Expert Working Groups (EWG) will be discussed. A proposal to move oversight for the EWGs from the Center for Drug Evaluation and Research (CDER) to NCTR will also be reviewed. Representatives from CDER and industry will present perspectives on the proposed change in oversight. An earlier version of this proposal was discussed at the June 2001 and August 2002 meetings of the SAB. The Board will also receive updates on the activities of the Cardiotoxicity and Vascular Injury EWGs.

Procedure: On June 19, 2003, from 9 a.m. to 4:45 p.m., and June 20, 2003, from 9 a.m. to 11:45 a.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by June 6, 2003. Oral presentations from the public will be scheduled between approximately 10:45 a.m. and 11:45 a.m., on June 20, 2003. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before June 6, 2003, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On June 20, 2003, from 11:45 a.m. to 12:15 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). This portion of the meeting will be closed to permit discussion of information concerning individuals associated with the research programs at NCTR.

Persons attending FDA's advisory committee meetings are advised that the

agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Leonard M. Schechtman at least 14 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: May 3, 2003.

Peter J. Pitts

Associate Commissioner for External Relations.

[FR Doc. 03–11605 Filed 5–8–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03N–0077]

FDA Modernization Act of 1997; Modifications to the List of Recognized Standards, Recognition List Number: 008; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of April 28, 2003 (68 FR 22391). The document announced a publication entitled ''FDA Modernization Act of 1997; Modifications to the List of Recognized Standards, Recognition List Number; 008.'' The publication contains modifications the agency is making to the list of standards FDA recognizes for use in the premarket reviews. The document published with an inadvertent error. This document corrects that error.

DATES: May 9, 2003.

FOR FURTHER INFORMATION CONTACT: Joyce Strong, Office of Policy and Planning (HF–27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7010.

SUPPLEMENTARY INFORMATION: In FR Doc. 03–10417, appearing on page 22397 in the **Federal Register** of Monday, April 28, 2003, the following correction is made:

On page 22397, the section heading ''IV. Listing of New Entries'' is corrected to read ''III. Listing of New Entries.''

Dated: May 2, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–11498 Filed 5–8–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Fiscal Year 2003 Competitive Application Cycle for the Black Lung Clinics Program (BLCP) CFDA Number 93.965; HRSA–03–086

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of availability of funds.

SUMMARY: The Health Resources and Services Administration (HRSA) announces the availability of up to $250,000 to support one grant project to an eligible entity for the purpose of carrying out a program to seek out and provide services to active and inactive miners, in southwest Indiana, who were exposed to coal dust as a result of employment. The former grantee in southwest Indiana relinquished the grant on September 23, 2002. As a result, an interim grantee was identified. The project period for the interim grantee ends on June 30, 2003. Eligible entities are expected to provide services described below in ''Program Expectations. The Bureau of Primary Health Care (BPHC) intends to fund no more than one award.

Authorizing Legislation: The Black Lung Clinics Program (BLCP) was authorized by the Federal Mine Safety and Health Act of 1977 as amended by the Black Lung Benefits Reform Act of 1977 (Pub. L. 95–239), in order to provide treatment and rehabilitation for individuals who currently or formerly worked within a coal or other mining industry and, as a result, were exposed to coal dust. It provides the authority for competitive grants to States, private, or public entities to provide the services listed below in ''Program Expectations'' to the population described above. Services may be provided either directly or through formal arrangements with appropriate health care providers. The implementing regulations for the BLCP may be found at 42 CFR part 55a.

DATES: The intended timeline for application submission, review and award are as follows: June 13, 2003, application deadline; July 31, 2003, grant awards announced.

Applications will be considered on time if they are: (1) Received on or before the established deadline date; or (2) postmarked on or before the deadline date given in the **Federal Register** notice. Late applications will be returned to the applicant. Applicants should obtain a legibly dated receipt from a commercial carrier or the U.S. Postal Service or request a legibly dated U.S. Postal Service postmark. Private metered postmarks shall not be accepted as proof of timely mailing. Applications sent to any address other than that specified below are subject to being returned. Applicants will receive notification of their application receipt. Electronic submission is not available for this program announcement.

Application Requests: To receive a complete application kit (*i.e.,* application instructions, necessary forms, and application review criteria), contact the HRSA Grants Application Center at:

HRSA Grants Application Center, 901 Russell Avenue, Suite 450, Gaithersburg, MD 20879. Phone: 1–877–HRSA–123 (1–877–477–2123). Fax: 1–877–HRSA–345 (1–877–477–2345). E-mail: *hrsagac@hrsa.gov.*

When contacting the HRSA Grants Application Center (GAC) please use the following program announcement when requesting application materials: HRSA–03–086. Applications must be submitted to the HRSA GAC. Applicants should note that beginning April 1, 2003, HRSA will begin accepting grant applications online. Please refer to the HRSA grants schedule at *http://www.hrsa.gov/grants.htm* for more information. Applications *must be postmarked* by the due date as specified above for each program area.

Eligible Applicants: The following entities are eligible to apply for the funds described in this notice:

- Any State, private, or public entities, including faith-based and community-based organizations, proposing to serve miners or coal miners, in southwest Indiana, exposed to coal dust as a result of employment.

Program Expectations: The purpose of the BLCP is to improve the health status of miners or coal miners exposed to coal dust as a result of employment and to increase coordination with other services and benefits programs to meet the health-related needs of this population.

The following is a list of core services that must be provided by all grantees:

- Primary care, including screening, diagnosis, treatment, and rehabilitation
- Patient and family education and counseling
- Outreach