records in a system of records are matched with other Federal, State, or local government records. It requires Federal agencies involved in computer matching programs to:

1. Negotiate written agreements with the other agencies participating in the matching programs;
2. Obtain the Data Integrity Boards (DIB) approval of the match agreements;
3. Furnish detailed reports about matching programs to Congress and OMB;
4. Notify applicants and beneficiaries that the records are subject to matching; and,
5. Verify match findings before reducing, suspending, terminating, or denying an individual's benefits or payments.

B. CMS Computer Matches Subject to the Privacy Act

CMS has taken action to ensure that all of the computer matches programs that this agency participates in comply with the requirements of the Privacy Act of 1974, as amended.

Dated: May 20, 2004.

Mark B. McClellan,

Administrator.

COMPUTER MATCH NO. 2001–04

NAME:

''Verification of TRICARE Eligibility''.

SECURITY CLASSIFICATION:

Level Three Privacy Act Sensitive.

PARTICIPATING AGENCIES:

Centers for Medicare & Medicaid Services (CMS); and Department of Defense (DoD).

AUTHORITY FOR CONDUCTING MATCHING PROGRAM:

This Computer Matching Agreement is executed to comply with the Privacy Act of 1974 (5 U.S.C. 552a), as amended, the Office of Management and Budget (OMB) Circular A–130, entitled ''Management of Federal Information Resources'' (61 FR 6435, February 20, 1996), and OMB guidelines pertaining to computer matching (54 FR 25818, June 19, 1989).

This agreement implements the information matching provisions of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2001 (Public Law (Pub. L.) 106–398) §§ 711 and 712; the NDAA for FY 1993 (Pub. L. 102–484) § 705, and the NDAA for FY 1992 (Pub. L. 102–190 §§ 704 and 713).

PURPOSE (S) OF THE MATCHING PROGRAM:

The purpose of this agreement is to establish the conditions, safeguards and procedures under which CMS will disclose Medicare Part A entitlement and Part B enrollment information to the Department of Defense (DoD), Defense Manpower Data Center (DMDC), Defense Enrollment and Eligibility Reporting System Office (DEERS), and the Office of the Assistant Secretary of Defense (Health Affairs) / TRICARE Management Activity (TMA). This disclosure will provide TMA with the information necessary to determine if an individual is eligible to receive extended TRICARE coverage.

Current law requires TMA to provide health care and medical benefits to Medicare eligible beneficiaries who are enrolled in the medical insurance program under Part B of the Medicare program. In order for TMA to meet these requirements, CMS agrees to disclose Part A entitlement and Part B enrollment data on this dual eligible population, which will be used to determine a beneficiary's eligibility for care under TRICARE. DEERS will receive the results of the computer match and provide the information provided to TMA for use in its program.

CATEGORIES OF RECORDS AND INDIVIDUALS COVERED BY THE MATCH:

DEERS will furnish CMS with an electronic file on a monthly basis extracted from DEERS' system of records identified as S322.50, entitled ''Defense Eligibility Records (DER),'' containing social security numbers (SSN) and date of birth for all DoD eligible beneficiaries whom may also be eligible for Medicare benefits. CMS will match the DEERS file against its ''Enrollment Database (EDB)'' system of records (formerly known as the Health Insurance Master Record), System No. 09–70–0502, and will validate the identification of the beneficiary by providing the Health Insurance Claims Number (HICN) that matches against the SSN and date of birth provided by DEERS. CMS will also provide the Medicare Part A entitlement and Part B enrollment status of the beneficiary. CMS's data will help TMA to determine a beneficiary's eligibility for care under TRICARE. DEERS will receive the results of the computer match and provide the information provided in the reply file to TMA for use in its program.

INCLUSIVE DATES OF THE MATCH:

The Computer Matching Program shall become effective no sooner than 40 days after the report of the Matching Program is sent to OMB and Congress, or 30 days after publication in the **Federal Register**, which ever is later. The matching program will continue for 18 months from the effective date and may be extended for an additional 12 months thereafter, if certain conditions are met.

[FR Doc. 04–11937 Filed 5–25–04; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002D–0350]

Guidance for Industry on Handling and Retention of Bioavailability and Bioequivalence Testing Samples; 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 ''Handling and Retention of BA and BE Testing Samples.'' The guidance is intended to provide recommendations for study sponsors and/or drug manufacturers, contract research organizations, site management organizations, clinical investigators, and independent third parties on the procedure for handling reserve samples from bioavailability (BA) and bioequivalence (BE) studies. The guidance clarifies how to distribute test articles and reference standards to testing facilities, how to randomly select reserve samples, and how to retain reserve samples.

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 Division of Dockets Management (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: Martin Yau, Center for Drug Evaluation and Research (HFD–45), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5458.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Handling and Retention of BA and BE Testing Samples.'' Following the generic drug crisis in the 1980s, FDA issued regulations to prevent possible bias and fraud in BA and BE testing by study sponsors and/or drug manufacturers (58 FR 25918, April 28, 1993). In the preamble to the final rule, the agency stated that the study sponsor should not separate out the reserve samples of the test article and reference standard prior to sending the drug product to the testing facility. This is to ensure that the reserve samples are in fact representative of the same batches provided by the study sponsor for the testing.

FDA's Division of Scientific Investigations and field investigators from the Office of Regulatory Affairs conduct inspections of clinical and analytical sites that perform BA and BE studies for sponsors and/or drug manufacturers seeking approval of generic and new drug products. A frequent finding from these inspections is the absence of reserve samples at the testing facility. In the **Federal Register** of August 21, 2002 (67 FR 54219), the agency issued a draft guidance entitled ''Handling and Retention of Bioavailability and Bioequivalence Testing Samples'' to clarify the responsibilities of the involved parties for retention of samples used in BA and BE studies. That draft guidance included recommendations for sampling techniques and responsibilities in various study settings. All comments received during the comment period have been carefully reviewed and changes were made to this final guidance where appropriate.

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 retention of BA and BE testing samples. 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 submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance at any time. Two copies of any mailed 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 Division of Dockets Management 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 either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default/htm.*

Dated: May 18, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–11828 Filed 5–25–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Maternal and Child Health Research Grants Review Committee; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: Maternal and Child Health Research Grants Review Committee.

Dates and Times: June 15 , 2004, 8:30 a.m. to 9:30 a.m.—open, June 15, 2004, 9:30 a.m. to 5 p.m.—closed, June 16, 2004, 8:30 a.m. to 5 p.m.—closed, June 17, 2004, 8:30 a.m. to 5 p.m.—closed.

Place: Hilton Garden Inn, 815 14th Street, NW., Washington, DC 20005.

Status: The meeting will be open to the public on Tuesday, June 15, 2004, from 8:30 a.m. to 9:30 a.m. The remainder of the meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(6), title 5 U.S.C., and the Determination of the Acting Deputy Associate Administrator for Management and Program Support, Health Resources and Services Administration (HRSA), pursuant to section 10(d) of the Federal Advisory Committee Act (Pub. L. 92–463).

Purpose: To review research grant applications in the program areas of maternal and child health, administered by HRSA's Maternal and Child Health Bureau (MCHB).

Agenda: The open portion of the meeting will cover opening remarks by the Director, Division of Research, Training and Education, MCHB, HRSA, who will report on program issues, congressional activities, and other topics of interest to the field of maternal and child health. The closed portion of the meeting will involve the review, discussion, and evaluation of grant applications containing information of a personal nature, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

For further information contact: Anyone wishing to obtain a roster of members, minutes of meetings, or other relevant information should write or contact Stella Yu, Sc.D., M.P.H., Executive Secretary, Maternal and Child Health Research Grants Review Committee, Room 18A–55, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–0695.

Dated: May 19, 2004.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 04–11829 Filed 5–25–04; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Eye Institute Special Emphasis Panel, Review of Conference Applications (R13s).

Date: May 24, 2004.

Time: 10 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5635 Fishers Lane, Bethesda, MD 20892.

Contact Person: Houmam H. Araj, PhD, Scientific Review Administrator, Division of Extramural Research, National Eye Institute, NIH, 5635 Fishers Lane, Suite 1300, Bethesda, MD 20892–9602, 301–451–2020, *haraj@mail.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institute of Health, HHS)

Dated: May 18, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04–11836 Filed 5–25–04; 8:45 am]

BILLING CODE 4140–01–M