

other by written request to terminate or modify the agreement.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Privacy Act of 1974, as amended; Computer Matching Program

AGENCY: Office of Child Support Enforcement (OCSE), ACF, DHHS.

ACTION: Notice of a computer matching program.

SUMMARY: In compliance with the Privacy Act of 1974, as amended by Public Law 100-503, the Computer Matching and Privacy Protection Act of 1988, we are publishing a notice of a computer matching program that OCSE will conduct on behalf of itself and State Agencies administering Unemployment Compensation programs under Federal or State law to facilitate the administration of such programs. The match will utilize National Directory of New Hires (NDNH) records and State Unemployment Compensation (UC) records.

DATES: OCSE will file a report of the subject matching program with the Committee on Homeland Security and Governmental Affairs of the Senate, the Committee on Government Reform and Oversight of the House of Representatives, and the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). The matching program will be effective as indicated below.

ADDRESSES: Interested parties may comment on this notice by writing to the Director, Division of Federal Systems, Office of Child Support Enforcement, Aerospace Building, 370 L'Enfant Promenade, SW., Washington, DC 20447. All comments received will be available for public inspection at this address.

FOR FURTHER INFORMATION CONTACT: Director, Division of Federal Systems, Office of Child Support Enforcement, Aerospace Building, 370 L'Enfant Promenade, SW., Washington, DC 20447. Telephone Number (202) 401-9271.

SUPPLEMENTARY INFORMATION: The Privacy Act (5 U.S.C. 552a), as amended, provides for certain protections for individuals applying for and receiving Federal benefits. The law regulates the use of computer matching

by Federal agencies when records in a system of records are matched with other Federal, state and local government records.

The Privacy Act requires agencies involved in computer matching programs to:

1. Negotiate written agreements with the other agency or agencies participating in the matching programs;
2. Provide notification to applicants and beneficiaries that their records are subject to matching;
3. Verify match findings before reducing, suspending, or terminating an individual's benefits or payments;
4. Furnish detailed reports to Congress and OMB; and
5. Establish a Data Integrity Board that must approve matching agreements.

This Computer Match meets the requirements of 5 U.S.C. 552a.

Dated: April 21, 2005.

David H. Siegel,

Acting Commissioner, Office of Child Support Enforcement.

Notice of Computer Matching Program

A. Participating Agencies

OSCE and State TANF programs.

B. Purpose of the Matching program

To exchange personal data for purposes of identifying individuals who are employed and also are receiving payments pursuant to TANF benefit programs being administered by State TANF programs and to verify continuing eligibility for TANF benefits.

OSCE will match public assistance records, furnished by State TANF programs, against information in the NDNH. After matching has been conducted, OSCE will provide match results to State TANF programs which will use this information to verify the continued eligibility of individuals to receive public assistance benefits and, if ineligible, to take such action, as may be authorized by law and regulation.

C. Authority for Conducting the Match

The authority for conducting the matching program is contained in section 453(j)(3) of the Social Security Act (42 U.S.C. 653(j)(3)).

D. Categories of Records and Individuals Covered by the Matching Program

The system of records maintained by the ACF under the privacy Act of 1974, as amended, 5 U.S.C. 552a, from which records will be disclosed for the purpose of this computer match, is the Location and Collection system of records, DHHS/OSCE No. 09-90-0074, last published in the **Federal Register** at

69 FR 31392 on June 3, 2004. The NDNH is maintained within the Location and Collection system of records. The matching program is a routine use under this system of records.

State TANF programs will provide to OSCE electronic files containing the names and other personal identifying data of TANF recipients. Upon receipt of the electronic files of State TANF recipients, OSCE will perform a computer match against the NDNH. The NDNH database consists of Quarterly Wage, New Hire, and Unemployment Insurance information. The results of the matching program will be furnished by OSCE to State TANF programs.

1. The electronic files provided by State TANF programs will contain data elements of the recipient's name and Social Security number (SSN).

2. OSCE will match the SSN on the State TANF file by computer against the NDNH database. Matching records, based on SSNs, will produce data elements of the individual's name, SSN, home address, and employment information.

E. Inclusive Dates of the Matching Program

The effective date of the matching agreement and date when matching may actually begin shall be July 1, 2005. This Computer Matching Notice is being published in the **Federal Register** at least 30 days prior to that date, and at least 40 days prior to that date OSCE shall send a matching program notice to the Congressional committees of jurisdiction under 5 U.S.C. 552a(o)(2)(A); and to OMB. By agreement between ACF and State TANF programs, the matching program will be in effect for 18 months from the effective date, with an option to renew for 12 additional months, unless one of the parties to the agreement advises the other by written request to terminate or modify the agreement.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D-0155]

Draft "Guidance for Industry: Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventive Vaccine Clinical Trials;" Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled "Guidance for Industry: Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventive Vaccine Clinical Trials," dated April 2005. The draft guidance provides sponsors of vaccine trials with recommendations on assessing the severity of clinical and laboratory abnormalities in healthy adult and adolescent volunteers enrolled in clinical trials. In particular, the draft guidance includes toxicity grading scale tables to use as a guideline for selecting the assessment criteria.

DATES: Submit written or electronic comments on the draft guidance by August 1, 2005 to ensure their adequate consideration in preparation of the final guidance. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800. See the

SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit written comments on the draft 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>.

FOR FURTHER INFORMATION CONTACT: Brenda R. Friend, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled "Guidance for Industry: Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventive Vaccine Clinical Trials" dated April 2005. The draft guidance provides sponsors of vaccine trials with toxicity grading scale tables as a guideline for

selecting the criteria to assess the severity of clinical and laboratory abnormalities in healthy adult and adolescent volunteers enrolled in clinical trials. The parameters in the tables are not necessarily warranted for every clinical trial of healthy volunteers. The parameters monitored should be appropriate for the specific study vaccine. In addition, the use of toxicity grading scales to categorize adverse events observed during clinical trials does not replace regulatory requirements to monitor, investigate, and report adverse events.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on this topic. 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 requirement of the applicable statutes and regulations.

II. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. Submit written or electronic comments to ensure adequate consideration in preparation of the final guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the draft 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 draft guidance at either <http://www.fda.gov/cber/guidelines.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: April 22, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of Laboratories Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) notifies Federal agencies of the laboratories currently certified to meet the standards of subpart C of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines). The Mandatory Guidelines were first published in the **Federal Register** on April 11, 1988 (53 FR 11970), and subsequently revised in the **Federal Register** on June 9, 1994 (59 FR 29908), on September 30, 1997 (62 FR 51118), and on April 13, 2004 (69 FR 19644).

A notice listing all currently certified laboratories is published in the **Federal Register** during the first week of each month. If any laboratory's certification is suspended or revoked, the laboratory will be omitted from subsequent lists until such time as it is restored to full certification under the Mandatory Guidelines.

If any laboratory has withdrawn from the HHS National Laboratory Certification Program (NLCP) during the past month, it will be listed at the end, and will be omitted from the monthly listing thereafter.

This notice is also available on the Internet at <http://workplace.samhsa.gov> and <http://www.drugfreeworkplace.gov>.

FOR FURTHER INFORMATION CONTACT: Mrs. Giselle Hersh or Dr. Walter Vogl, Division of Workplace Programs, SAMHSA/CSAP, Room 2-1035, 1 Choke Cherry Road, Rockville, Maryland 20857; 240-276-2600 (voice), 240-276-2610 (fax).

SUPPLEMENTARY INFORMATION: The Mandatory Guidelines were developed in accordance with Executive Order 12564 and section 503 of Public Law 100-71. Subpart C of the Mandatory Guidelines, "Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies," sets strict standards that laboratories must meet in order to conduct drug and specimen validity tests on urine specimens for Federal agencies. To become certified, an applicant laboratory must undergo three rounds of performance testing plus an on-site inspection. To maintain that