at the point of repackaging is to be linked to the SNI applied at the point of manufacturing, and to the extent practicable, the SNI should be harmonized with international consensus standards for such an identifier (see section 505D(b)(2) of the act). The provisions in section 505D(b) of the act complement and build on FDA's longstanding efforts to further secure the U.S. drug supply.

The agency received 44 comments in response to our request for public comment on the draft guidance. FDA also sought public comment on specific questions related to development of an SNI by opening a docket to receive information (73 FR 14988, March 20, 2008). We received 59 comments from a range of stakeholders, including manufacturers, wholesalers, pharmacies, trade and health professional organizations, technology vendors, health professionals, consumers, and State governments. We also shared both of these requests with State governments, other Federal agencies, and with foreign governments. The standards included in this guidance are based on information received in response to these requests for comment and the agency's familiarity with identification standards already in use for certain prescription biologics. All of the comments that we received have been considered and the guidance has been revised as appropriate.

The guidance is intended to be the first of several guidances and regulations that FDA may issue to implement section 505D of the act and its issuance is intended to assist with the development of standards and systems for identification, authentication, and tracking and tracing of prescription drugs. The guidance defines SNI for package-level identification only. For the purpose of this guidance, FDA considers the package to be the smallest unit placed into interstate commerce by the manufacturer or the repackager that is intended by that manufacturer or repackager, as applicable, for individual sale to the pharmacy or other dispenser of the drug product. Evidence that a unit is intended for individual sale, and thus constitutes a separate "package" for purposes of this guidance, would include evidence that it is accompanied by labeling intended to be sufficient to permit its individual distribution. This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115).

The guidance does not address how to link a repackager SNI to a manufacturer SNI, nor does it address standards for prescription drug SNI at levels other than the package-level including, for example, the case and pallet levels. Standards for track and trace, authentication, and validation are also not addressed in this guidance because this guidance only addresses the standardized numerical identifier itself and not implementation or application issues.

The guidance represents the agency's current thinking on standards for drug supply chain security-standardized numerical identification for prescription drug packages. 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. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information regarding labeling requirements for expiration date and lot numbering in 21 CFR. §§ 211.130, 211.137, 201.17, and 201.18 have been approved under OMB Control No. 0910–0139, and in §§ 610.60 and 610.61 have been approved under OMB Control No. 0910–0338.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments regarding this document. Submit a single copy of electronic 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 brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/Guidance/index.htm*, *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*, or *http://www.regulations.gov*.

Dated: March 23, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–6863 Filed 3–26–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Privacy Act of 1974; Report of an Altered System of Records

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

ACTION: Notice of an Altered System of Records (SOR).

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, the Health Resources and Services Administration (HRSA) is publishing notice of a proposal to alter the system of records for Health Professions Planning and Evaluation (SORN #09–15–0046; 63FR14124).

The purpose of these alterations is to change the name, to update addresses, authority for maintenance, to improve clarity and to add a new routine use. The routine use is to allow the Department to use information in the system of records for responding to potential breaches to the security or confidentiality of records in the system. These changes will have no known or perceived adverse effects on individual privacy.

DATES: HRSA filed an altered system report with the Chair of the House Committee on Government Reform and Oversight, the Chair of the Senate Committee on Homeland Security and Governmental Affairs, and the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) on March 1, 2010. To ensure all parties have adequate time in which to comment, the altered systems, including the routine uses, will become effective 30 days from the publication of the notice or 40 days from the date it was submitted to OMB and Congress, whichever is later, unless HRSA receives comments that require alterations to this notice.

ADDRESSES: Please address comments to Associate Administrator, Health Resources and Services Administration, 5600 Fishers Lane, Room 9A–18, Rockville, Maryland 20857. Comments received will be available for inspection at this same address from 9 a.m. to 3

p.m. (Eastern Standard Time Zone), Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Director, Office of Workforce Policy and Performance Management, 5600 Fishers Lane, Room 9A–18, Rockville, MD (301) 443–0367. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: HRSA has completed the annual review of its systems of records and is publishing changes which affect the public's right or need to know, such as routine uses, system deletions, title changes, and changes in the system location of records, or the addresses of systems managers.

1. System of records, 09–15–0046, Health Professions Planning and Evaluation, has been renamed to Health Professions Analysis and Evaluation. The System Manager's name and address has been updated, and the list of record storage has added "electronic files," and card files, microfilm, and microfiche have been deleted as these storage devices have not been utilized. Under notification and records access procedures, the words "for proof of identity" have been added to clarify the requirements for identification.

2. A new routine use (#5) has been added to implement OMB Memorandum M–07–16, Safeguarding Against and Responding to the Breach of Personally Identifiable Information.

3. The authorities for maintenance of the system have been updated and modified. Authorized personnel are limited to HRSA staff and contractor personnel directly involved in data collection, compilation, and analysis. The specific data items collected and maintained will be determined by the needs of the individual project and restricted to the minimum set necessary to accomplish project objectives.

Dated: March 17, 2010.

Mary K. Wakefield,

Administrator.

System Number: 09–15–0046

SYSTEM NAME:

Health Professions Analysis and Evaluation, HHS/HRSA/BHPr.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

This system of records is an umbrella system comprising separate sets of records located either in the organizations responsible for conducting evaluations or at the sites of programs or activities under evaluation. Locations include the Health Resources and Services Administration (HRSA) facilities in Rockville, Maryland (*see* address of System Manager below), or facilities of contractors of HRSA. Write to the System Manager for a list of current locations.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Health professionals and students in the various health professions who are the subjects of studies or evaluations being conducted by HRSA. Physicians, dentists, pharmacists, optometrists, podiatrists, veterinarians, public health personnel, audiologists, speech pathologists, health care administration personnel, nurses, allied health personnel, medical technologists, chiropractors, clinical psychologists, and other health personnel may be included.

CATEGORIES OF RECORDS IN THE SYSTEM:

Name, address, health profession, education history, academic grades, employment history, nationality, race, ethnicity, economic background, and sex. The specific data items collected and maintained are determined by the needs of the individual project and are restricted to the minimum set necessary to accomplish project objectives.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Authority is found in the following sections of the Public Health Service Act; section 761 of the Public Health Service Act (42 U.S.C. 294n), Health Professions Workforce Information and Analysis; section 792 of the Public Health Service Act (42 U.S.C. 295k), Health Professions Data.

PURPOSE(S) FOR RECORDS IN THIS SYSTEM:

The Health Resources and Services Administration uses various records in this system to identify problems in the health care training and delivery systems to plan programs to correct those problems, and to evaluate the effectiveness of the resultant programs. The agency assesses the current supply of health professionals and predicts the supply needs of the future. The agency determines nationwide requirements as well as the needs of specific areas. The agency also collects data on the educational system which supplies health professionals and on specific health education programs. The data are used to develop and test new methods of training and utilizing health professionals.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Disclosure may be made to a congressional office from the record of an individual in response to a verified inquiry from the congressional office made at the written request of that individual.

2. A record may be disclosed for a research purpose, when the Department: (a) Has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained; (b) Has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring; (c) Has required the recipient to—(1) Establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except—(A) In emergency circumstances affecting the health or safety of any individual, (B) for use in another research project, under these same conditions, and with written authorization of the Department, (C) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (D) when required by law; and (d) Has secured a written statement attesting to the recipient's understanding of, and willingness to abide by these provisions.

3. Disclosure may be made to HHS contractors and their staff, in order to accomplish any of the purposes of the system of records. The recipients are required to protect such records from improper disclosure and to maintain Privacy Act safeguards.

4. The Department may disclose information from this system of records to the Department of Justice, or to a court or other tribunal, when (a) HHS, or any component thereof; or (b) Any HHS employee in his or her official capacity; or (c) Any HHS employee in his or her individual capacity where the Department of Justice (or HHS, where it is authorized to do so) has agreed to represent the employee; or (d) The United States or any agency thereof where HHS determines that the litigation is likely to affect HHS or any of its components, is a party to litigation

or has an interest in such litigation, and HHS determines that the use of such records by the Department of Justice, the court or other tribunal is relevant and necessary to the litigation and would help in the effective representation of the governmental party, provided, however, that in each case, HHS determines that such disclosure is compatible with the purpose for which the records were collected.

5. The Department may disclose information to appropriate Federal agencies and Department contractors that have a need to know the information for the purpose of assisting the Department's efforts to respond to a suspected or confirmed breach of the security or confidentiality of information maintained in this system of records, and the information disclosed is relevant and necessary for that assistance.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

None.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

1. *Storage:* Electronic files, file folders, magnetic tape, and disk storage. The needs of each project determine the types of storage actually used.

2. *Retrievability:* By name or by an assigned number.

3. *Safeguards:* Locked building, locked rooms, locked file cabinets, personnel screening, locked computer rooms and computer tape vault, guard service, password protection of automated records and limited access to only authorized personnel may be used. Particular safeguards are selected as appropriate to the type of records included in each project. Authorized personnel are limited to HRSA staff and contractor personnel directly involved in data collection, compilation, and analysis. (Safeguards are in accordance with Part 6, ADP Systems Security, of the Department's Information Resources Management Manual, with Chapter 45–13, Safeguarding Records Contained in Systems of Records, of the Department's General Administration Manual, and with supplementary Chapter PHS. 45–13.)

4. *Retention and Disposal:* The contractor removes personal identifiers and destroys the records when they are no longer needed, as appropriate to the specific project. (Records may be retired to a Federal Records Center and subsequently disposed of in accordance with the Records Control Schedule of the Health Resources and Services Administration). You may obtain a copy of the disposal standard for a particular project by writing to the System Manager.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Office of Workforce Policy and Performance Management, Bureau of Health Professions, HRSA, 5600 Fishers Lane, Room 9A–18, Rockville, MD 20857.

NOTIFICATION PROCEDURE:

Requests concerning whether the system contains records about an individual should be made to the Systems Manager.

Request in person: A subject individual who appears in person at a specific location seeking access or disclosure of records relating to him/her shall provide his/her name, current address, and at least one piece of tangible identification such as driver's license, passport, voter registration card, or union card. Identification papers with current photographs are preferred but not required. Additional identification may be requested when there is a request for access to records which contain an apparent discrepancy between information contained in the records and that provided by the individual requesting access to the records. Where the subject individual has no identification papers, the responsible agency official shall require that the subject individual certify in writing that he/she is the individual who he/she claims to be and that he/she understands that the knowing and willful request or acquisition of a record concerning an individual under false pretenses is a criminal offense subject to a $5,000 fine.

Requests by mail: A written request must contain the name and address of the requester and his/her signature, which is either notarized to verify his/her identify or includes a written certification that the requester is a person he/she claims to be and that he/she understands that the knowing and willful request or acquisition of records pertaining to an individual under false pretenses is a criminal offense subject to a $5,000 fine.

Requests by telephone: Because positive identification of the caller cannot be established, no requests by telephone will be honored.

RECORDS ACCESS PROCEDURES:

To obtain access to your record, contact the System Manager and provide suitable identification for proof of identity, a reasonable description of the record and, if possible, information about the specific project. You may also request a list of accountable disclosures that have been made of your record.

CONTESTING RECORDS PROCEDURES:

To correct your record, contact the System Manager and provide:

a. Suitable identification for proof of identity,

b. A reasonable description of the record,

c. The specific information you want corrected, and

d. A precise description of the correction, with supporting justification. The right to contest records is limited to information which is incomplete, irrelevant, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Subject individuals, State and local health departments, other health providers, health professions schools, and health professions associations may provide information depending on the individual project involved.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE PRIVACY ACT:

None.

[FR Doc. 2010–6878 Filed 3–26–10; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0156]

Advancing the Development of Diagnostic Tests and Biomarkers for Tuberculosis; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA) in partnership with the Centers for Disease Control and Prevention (CDC) and the National Institute of Allergy and Infectious Diseases (NIAID) is announcing a public workshop entitled "Advancing the Development of Diagnostic Tests and Biomarkers for Tuberculosis (TB)." The purpose of the workshop is to provide an environment for FDA, CDC, and NIAID to engage other interested parties in identifying intellectual and procedural gaps in the current development of TB diagnostic tests, and in exploring models and strategies that would expedite the development of new diagnostic tests and biomarkers for TB.

Date and Time: The public workshop will be held on June 7 and 8, 2010, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at the National Labor College,