

labeling of topically applied cosmetic products that contain an AHA as an ingredient. 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 the approach satisfies the requirements of applicable statutes and regulations.

III. Comments on Guidance

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. 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 brackets in the heading of this document. The guidance and 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

Copies of this guidance also are available on the Internet at <http://www/cfsan.fda.gov/~dms/guidance.html>.

V. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Sah, A., S. Mukherjee and R. R. Wickett, "An In Vitro Study of the Effects of Formulation Variables and Product Structure on Percutaneous Absorption of Lactic Acid," *Journal of Cosmetic Science*, vol. 49, pp. 257–273, 1998.

2. Kraeling, M. E. K. and R. L. Bronaugh, "In Vitro Percutaneous Absorption of Alpha Hydroxy Acids in Human Skin," *Journal of the Society of Cosmetic Chemists*, vol. 48, pp. 187–197, 1997.

3. Yates, R. L. and D. C. Havery, "Determination of Phenol, Resorcinol, Salicylic Acid and α -Hydroxy Acids in Cosmetic Products and Salon Preparations," *Journal of Cosmetic Science*, vol. 50, pp. 315–325, 1999.

4. Andersen, F. A., ed., "Final Report on the Safety Assessment of Glycolic Acid, Ammonium, Calcium, Potassium, and Sodium Glycolates, Methyl, Ethyl, Propyl, and Butyl Glycolates, and Lactic Acid, Ammonium, Calcium, Potassium, Sodium, and TEA-Lactates, Methyl, Ethyl, Isopropyl, and Butyl Lactates, and Lauryl, Myristyl, and Cetyl Lactates," *International Journal of Toxicology*, vol. 17, supplement 1, pp. 1–241, 1998.

5. Wamer, W., Office of Cosmetics and Colors, CFSAN, Review of Documents from Access Business Group: Aupperlee, D., et al., "The Effects of UV Light on Skin Pre-Treated With Alpha Hydroxy Acid Moisturizers," and Thomas J. Stevens and Associates, "The

Effects of Repetitive Cutaneous Application of Test Materials Containing Alpha Hydroxy Acid on the Sensitivity of Skin to Ultraviolet (UV) Light," July 1, 2003.

Dated: December 29, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–381 Filed 1–7–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Privacy Act of 1974; New System of Records

AGENCY: Health Resources and Services Administration, DHHS.

ACTION: Notification of a new system of records.

SUMMARY: In accordance with the requirements of the Privacy Act, the Health Resources and Services Administration (HRSA) is publishing notice of a proposal to add a new system of records. The new system of records, "State-Provided Physician Records for the Application Submission & Processing System, SDB, BHPr, HRSA," will cover health care practitioners who are the subjects of databases collected and maintained by State Primary Care Offices/Associations. Such health care practitioners include physicians (both M.D.s and D.O.s), licensed or otherwise authorized by a State to provide health care services. This system of records is required to comply with the implementation directives of the Act, Public Law 108–20. The records will be used to support the Application Submission and Processing System electronic application for the development, submission, and review of applications for HPSAs and MUPs. The most critical requirement for accurate designation determinations is accurate data on the location of primary care providers relative to the population. To this end, SDB continually tries to obtain the latest data on primary care providers and their practice location(s) at the lowest geographical level possible for use in the designation process, with the objective of minimizing the level of effort required on the part of States and communities seeking designations.

DATES: HRSA invites interested parties to submit comments on the proposed New System of Records on or before February 22, 2005. As of the date of the publication of this Notice, HRSA has sent a Report of New System of Records to Congress and to the Office of

Management and Budget (OMB). The New System of Records will be effective 40 days from the date submitted to OMB unless HRSA receives comments that would result in a contrary determination.

ADDRESSES: Please address comments to Health Resources and Services Administration (HRSA) Privacy Act Officer, 5600 Fishers Lane, Room 14A–20, Rockville, Maryland 20857; telephone (301) 443–3780. This is not a toll-free number. Comments received will be available for inspection at this same address from 9 a.m. to 3 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Associate Administrator, Bureau of Health Professions, Health Resources and Services Administration (HRSA), 5600 Fishers Lane, Room 8–05, Rockville, Maryland 20857; telephone (301) 443–5794. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: The Health Resources and Services Administration (HRSA) proposes to establish a new system of records: "State-Provided Physician Records for the Application Submission & Processing System, SDB, BHPr, HRSA." The new system of records, "State-Provided Physician Records for the Application Submission & Processing System, SDB, BHPr, HRSA," will cover health care practitioners who are the subjects of databases collected and maintained by State Primary Care Offices/Associations. Such health care practitioners include physicians (both M.D.s and D.O.s), licensed or otherwise authorized by a State to provide health care services. The records will be used to support the Application Submission and Processing System electronic application for the development, submission, and review of applications for HPSAs and MUPs. The most critical requirement for accurate designation determinations is reliable data on the location of primary care providers relative to the population. To this end, SDB continually tries to obtain the latest data on primary care providers and their practice location(s) at the lowest geographical level possible for use in the designation process, with the objective of minimizing the level of effort required on the part of States and communities seeking designations. The system will include records that show a value for each of the following fields for all of the physicians that are included in each States' database: Provider ID (System-Assigned); Provider Type; Provider Status; First Name; Middle Name; Last Name; Suffix; Physician License Number; Specialty Code; Visa

Status; Federal Employee Status; National Health Service Corps Status; MD/DO; AMA ID; AOA ID; Hospital Privileges Status; Gender; Source Type; Address 1; Address 2; Address 3; City; State; Zip; FIPS State; FIPS County; Census Tract; Minor Civil Division; Longitude; Latitude; Address FTE; Office Visits (Per Year); New Patients Waiting Time For Appointments (days); Current Patients Waiting Time For Appointments (days); Average Wait for New Patient (hours); Average Wait for Current Patient (hours); Patient Percent—Homeless; Patient Percent—Medicaid; Patient Percent—Migrant Farm worker; Patient Percent—Native American; Patient Percent—Sliding Fee Scale; Patient Percent—Language Barrier Present; Patient Percent—Migrant/Seasonal Farm worker; Patient Percent—Other Population; Medicaid Claims; Hours Given Include Time Spent in Hospital; Accepts New Patients; Tour Hours in Direct Patient Care for this Address; Sub Specialty; Sub Specialty Percent; Language 1; Language 1 Percent; Language 2; Language 2 Percent; Language 3; and Language 3 Percent.

Disclosure of these records may be made to HRSA employees in order to accomplish the purposes for which the records are collected. The users are required to comply with the requirements of the Privacy Act with respect to such records. Also, each State Primary Care Office (and a few Primary Care Associations) may have access to provider data within their own state. These users will also have access to bordering states' data (one county-deep) at an aggregate level only. Disclosure may also be made to contractors engaged by the Department to geocode the physicians' address so that it may be seen on a computerized map, or to load the provider data into the Application Submission and Processing Systems. All such contractors shall be required to maintain Privacy Act safeguards with respect to such records and return all records to HRSA.

This system of records is required to comply with the implementation directives of the Act, Public Law 108–20.

The following notice is written in the present tense, rather than in the future tense, in order to avoid the unnecessary expenditure of public funds to republish the notice after the system becomes effective.

Dated: December 23, 2004.

Elizabeth M. Duke,

Administrator, Health Resources and Services Administration.

09–15–0066

SYSTEM NAME:

State-Provided Physician Records for the Application Submission & Processing System, SDB, BHP, HRSA

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

System Manager is located in Shortage Designation Branch, Office of Workforce Evaluation and Quality Assurance, Bureau of Health Professions, Health Resources and Services Administration, 5600 Fishers Lane, Room 8C–26, Rockville, Maryland 20857. Actual computer server is located in Office of Information Technology, Health Resources and Services Administration, 5600 Fishers Lane, Room 10A–08, Rockville, Maryland 20857.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Health care practitioners who are the subjects of databases collected and maintained by State Primary Care Offices/Associations. Such health care practitioners include physicians (both M.D.s and D.O.s), licensed or otherwise authorized by a State to provide health care services.

CATEGORIES OF RECORDS IN THE SYSTEM:

The system will include records that show a value for each of the following fields for all of the physicians that are included in each States' database:

- Provider ID (System-Assigned)
- Provider Type
- Provider Status
- First Name
- Middle Name
- Last Name
- Suffix
- Physician License Number
- Specialty Code
- Visa Status
- Federal Employee Status
- National Health Service Corps Status
- MD/DO
- AMA ID
- AOA ID
- Hospital Privileges Status
- Gender
- Source Type
- Address 1
- Address 2
- Address 3
- City
- State
- Zip

- FIPS State
- FIPS County
- Census Tract
- Minor Civil Division
- Longitude
- Latitude
- Address FTE
- Office Visits (Per Year)
- New Patients Waiting Time For Appointments (days)
- Current Patients Waiting Time For Appointments (days)
- Average Wait for New Patient (hours)
- Average Wait for Current Patient (hours)
- Patient Percent—Homeless
- Patient Percent—Medicaid
- Patient Percent—Migrant Farmworker
- Patient Percent—Native American
- Patient Percent—Sliding Fee Scale
- Patient Percent—Language Barrier Present
- Patient Percent—Migrant/Seasonal Farmworker
- Patient Percent—Other Population
- Medicaid Claims
- Hours Given Include Time Spent in Hospital?
- Accepts New Patients?
- Tour Hours in Direct Patient Care for this Address
- Sub Specialty
- Sub Specialty Percent
- Language 1
- Language 1 Percent
- Language 2
- Language 2 Percent
- Language 3
- Language 3 Percent

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 CFR, chapter 1, part 5—Designation of Health Professional Shortage Areas and section 332 of the Public Health Service (PHS) Act provide that the Secretary of Health and Human Services shall designate health professional shortage areas, (HPSAs), and/or Medically Underserved Populations (MUPs), based on criteria established by regulation. The authority for designation of HPSAs is delegated to the Bureau of Health Profession's Shortage Designation Branch (SDB). Criteria and the process used for designation of HPSAs and/or MUPs were developed in accordance with the requirements of section 332 of the PHS Act. Designation as a HPSA is a prerequisite for application for the National Health Service Corps recruitment assistance. To accomplish this task, the SDB relies on data specified in 42 CFR part 5 and HPSA and/or MUP guidelines, to review applications submitted by State Primary Care Offices (PCO) and their affiliates for designation status.

PURPOSE(S):

The sole purpose of the system is to support the Application Submission and Processing System electronic application for the development, submission, and review of applications for HPSAs and MUPs. The most critical requirement for accurate designation determinations is reliable data on the location of primary care providers relative to the population. To this end, SDB continually tries to obtain the latest data on primary care providers and their practice location(s) at the lowest geographical level possible for use in the designation process, with the objective of minimizing the level of effort required on the part of States and communities seeking designations.

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

1. Disclosure may be made to HRSA employees in order to accomplish the purposes for which the records are collected. The users are required to comply with the requirements of the Privacy Act with respect to such records.
2. Each state Primary Care Office (and a few Primary Care Associations) may have access to provider data within their own state. These users will also have access to bordering states' data (one county-deep) at an aggregate level only.
3. Disclosure may be made to contractors engaged by the Department to geocode the physicians' address so that it may be seen on a computerized map, or to load the provider data into the Application Submission and Processing Systems. All such contractors shall be required to maintain Privacy Act safeguards with respect to such records and return all records to HRSA.

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

Records are maintained in file folders and in computer data files.

RETRIEVABILITY:

Retrieval of physician records is by use of personal identifiers used when entering the system.

SAFEGUARDS:

1. *Authorized users:* Access to records is limited to designated HRSA and PCO/A staff. These employees are the only authorized users. HRSA maintains current lists of authorized users.
2. *Physical Safeguards:* All computer equipment and files are stored in areas

where fire and life safety codes are strictly enforced. All automated and non-automated documents are protected on a 24-hour basis. Perimeter security includes intrusion alarms, on-site guard force, random guard patrol, key/passcard/combination controls, and receptionist controlled area. Hard copy files are maintained in a file room used solely for this purpose with access limited by combination lock to authorized users identified above. Computer files are password protected and are accessible only by use of computers which are password protected.

3. *Procedural Safeguards:* A password is required to access computer files. All users of personal information in connection with the performance of their jobs protect information from public view and from unauthorized personnel entering an unsupervised area. All authorized users sign a "Rules of Behavior" document. All passwords, keys and/or combinations are changed when a person leaves or no longer has authorized duties. Access to records is limited to those authorized personnel trained in accordance with the Privacy Act and ADP security procedures. The safeguards described above were established in accordance with DHHS Chapter 45-13 and supplementary chapter PHS hf:45-13 of the General Administration Manual; and the DHHS Information Resources Management Manual, Part 6, "ADP Systems Security."

RETENTION AND DISPOSAL:

Retention and disposal is in accordance with the HRSA records retention schedule. Contact the System Manager at the following address for further information.

SYSTEM MANAGER(S) AND ADDRESS:

Debra Small, ASAPS System Manager, Public Health Analyst, Shortage Designation Branch, Office of Workforce Evaluation and Quality Assurance, Bureau of Health Professions, Health Resources and Services Administration, 5600 Fishers Lane, Room 8C-26, Rockville, Maryland 20857.

NOTIFICATION PROCEDURE:

Write to the System Manager to determine if a record exists. The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a

criminal offense under the Act, subject to a fine.

RECORD ACCESS PROCEDURE:

To obtain access to a record, contact the System Manager at the above specific address. Requesters should provide the same information as is required under the Notification Procedures above. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURES:

Write to the official specified under Notification Procedures above, and reasonably identify the record and specify the information being contested, the corrective action sought, and your reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant. The right to contest records is limited to information which is incomplete, incorrect, untimely, or irrelevant.

RECORD SOURCE CATEGORIES:

Data are collected from the State Primary Care Offices and a few State Primary Care Associations.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 05-447 Filed 1-7-05; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****Government-Owned Inventions; Availability for Licensing**

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive