

in medically underserved communities (section 737(c) of the PHS Act).

The estimated response burden is as follows:

Form	Number of respondents	Responses per respondents	Hours per response	Total burden hours
SDS Application .....	600	1	13	7,800
SDS Report .....	600	1	1	600
Total .....	600	1	14	8,400

E-mail comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail to the HRSA Reports Clearance Officer, Room 10-33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: April 6, 2010.

**Sahira Rafiullah,**

*Director, Division of Policy and Information Coordination.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0031]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Export of Medical Devices-Foreign Letters of Approval

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by May 17, 2010.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or e-mailed to [oira\\_submission@omb.eop.gov](mailto:oira_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0264. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, [Daniel.Gittleson@fda.hhs.gov](mailto:Daniel.Gittleson@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

#### Export of Medical Devices-Foreign Letters of Approval (OMB Control Number 0910-0264)—Extension

Section 801(e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 381(e)(2)) provides for the exportation of an unapproved device under certain circumstances if the exportation is not contrary to the public health and safety and it has the approval of the foreign country to which it is intended for export. Requesters

communicate (either directly or through a business associate in the foreign country) with a representative of the foreign government to which they seek exportation, and written authorization must be obtained from the appropriate office within the foreign government approving the importation of the medical device. An alternative to obtaining written authorization from the foreign government is to accept a notarized certification from a responsible company official in the United States that the product is not in conflict with the foreign country's laws. This certification must include a statement acknowledging that the responsible company official making the certification is subject to the provisions of 18 U.S.C. 1001. This statutory provision makes it a criminal offense to knowingly and willingly make a false or fraudulent statement, or make or use a false document, in any manner within the jurisdiction of a department or agency of the United States. The respondents to this collection of information are companies that seek to export medical devices. FDA's estimate of the reporting burden is based on the experience of FDA's medical device program personnel.

In the **Federal Register** of January 26, 2010 (75 FR 4086), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Section of the Federal Food, Drug, and Cosmetic Act	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	Total Operating and Maintenance Costs <sup>2</sup>
801(e)(2)	38	1	38	3	114	\$6,250

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup> Due to a clerical error, the operating and maintenance costs that appeared in the notice issued in the **FEDERAL REGISTER** of January 26, 2010, were reported as zero. The correct figure is in Table 1 of this document.

Dated: April 9, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010-8572 Filed 4-14-10; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### National Advisory Council on Migrant Health; 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:* National Advisory Council on Migrant Health.

*Dates and Times:* May 3, 2010, 8:30 a.m. to 5 p.m. May 4, 2010, 8:30 a.m. to 5 p.m.

*Place:* Hard Rock Hotel San Diego, 207 5th Avenue, San Diego, California 92101, Telephone: 619-702-3000, Fax: 877-344-7625.

*Status:* The meeting will be open to the public.

*Purpose:* The purpose of the meeting is to discuss services and issues related to the health of migrant and seasonal farmworkers and their families and to formulate recommendations for the Secretary of Health and Human Services.

*Agenda:* The agenda includes an overview of the Council's general business activities. The Council will also hear presentations from experts on farmworker issues, including the status of farmworker health at the local and national levels.

The Council meeting is being held in conjunction with the National Farmworker Conference sponsored by the National Association of Community Health Centers, which is being held in San Diego, California, May 5-7, 2010.

Agenda items are subject to change as priorities indicate. **FOR FURTHER INFORMATION CONTACT:** Gladys Cate, Office of Minority and Special Populations, Bureau of Primary Health Care, Health Resources and Services Administration, 5600 Fishers Lane, Maryland 20857; telephone (301) 594-0367.

Dated: April 7, 2010.

**Sahira Rafiullah,**

*Director, Division of Policy and Information Coordination.*

[FR Doc. 2010-8624 Filed 4-14-10; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

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

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

**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 an existing System of Records. The existing system of records, "State-Provided Physician Records for the Application Submission & Processing System (ASAPS), Office of Shortage Designation (OSD), Bureau of Health Professions (BHP), HRSA," SORN #09-15-0066, originally published on January 10, 2005, covers 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, dentists, and mental health professionals. This State collected data may now also be made available to contractors employed by the OSD to assist in the application review process. The States affected have signed a Data Use Agreement permitting the contractors to have access to their data.

The purposes of these alterations are to update the system manager location, authority for maintenance of the system, categories of individuals covered by the system and categories of records in the system. Additionally, HRSA is adding new routine uses numbers 4 and 5, to include the reviewing and processing assistance from contractors and the breach notification language. This system of records is required to comply with the implementation directives of Section 332 of the Public Health Service Act. The records will be used to support the ASAPS 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 health care providers relative to the population. To this end, OSD continually tries to obtain the latest data on primary care, dental, and mental health 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 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 system, 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 the Application Submission & Processing System (ASAP) System Manager, Office of Shortage Designation, Bureau of Health Professions, Health Resources and Services Administration, 5600 Fishers Lane, Room 8A-08, Rockville, Maryland 20857; telephone (301) 594-4473. 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., (Eastern Standard Time zone), Monday through Friday.

**FOR FURTHER INFORMATION CONTACT:** Please contact the ASAPS, System Manager, Office of Shortage Designation, Bureau of Health Professions, Health Resources and Services Administration (HRSA), 5600 Fishers Lane, Room 8A-08, Rockville, Maryland 20857; telephone (301) 594-4473. This is not a toll-free number.

**SUPPLEMENTARY INFORMATION:** The following changes/additions are being made to the current System of Records Routine Uses: (4) The Office of Shortage Designation (OSD) has contracted with a vendor to assist OSD in the review and processing of the HPSA and/or MUA/P applications received by the State offices. Such access will only be granted to the contractors with the States' written permission, and all such contractors shall be required to sign a Rules of Behavior document, maintain Privacy Act safeguards with respect to such records, and return all records to HRSA; (5) The SORN will now include specific language to appropriate Federal agencies and Department contractors that have a need to know the information for the purpose of assisting