

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Allergenic Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on November 5, 2013, from 9 a.m. to approximately 3:30 p.m. and on November 6, 2013, from 8:30 a.m. to approximately 2:45 p.m.

Location: FDA, 5630 Fishers Lane, Conference Room 1066, Rockville, MD 20857. For those unable to attend in person, the meeting will also be webcast. The webcast will be available at the following links:

November 5, 2013: <http://fda.yorkcast.com/webcast/Viewer/?peid=3074a2c9f7ac478db3303477ac1c146b1d>.

November 6, 2013: <http://fda.yorkcast.com/webcast/Viewer/?peid=2f114f7579ef42e8b4ca4523b0b26eb51d>.

Contact Person: Donald Jehn or Joanne Lipkind, Food and Drug Administration, 1401 Rockville Pike (HFM-71), Rockville, MD 20852, 301-827-0314, Donald.Jehn@fda.hhs.gov or Joanne.Lipkind@fda.hhs.gov, FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On November 5, 2013, the committee will meet in open session to discuss and make recommendations on the safety and efficacy of Oralair, a Sweet Vernal Grass, Perennial Ryegrass, Timothy Grass, Orchard Grass, and Kentucky Bluegrass Mixed Pollens Allergen Extract tablet for sublingual use, manufactured by Stallergenes. On November 6, 2013, the committee will meet in open session to discuss and make recommendations on the safety and efficacy of Grastek, a Timothy Grass Pollen Allergen Extract tablet for sublingual use, manufactured by Merck.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before October 29, 2013. Oral presentations from the public will be scheduled between approximately 12 noon and 12:30 p.m. on November 5, 2013, and between approximately 11:10 a.m. and 11:40 a.m. on November 6, 2013. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 21, 2013. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 22, 2013.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Donald Jehn or Joanne Lipkind at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 29, 2013

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-21555 Filed 9-4-13; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Health Resources and Services Administration
Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received within 30 days of this notice.

ADDRESSES: Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to OIRA_submission@omb.eop.gov or by fax to 202-395-5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at paperwork@hrsa.gov or call (301) 443-1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Develop and Implement UCARE4LIFE Message Library OMB No. 0915-xxxx-New.

Abstract: This project will develop and implement the UCARE4LIFE message library aimed at increasing HIV primary care retention rates for racial and ethnic minority youth aged 15 to 24, living with HIV/AIDS. The primary aims are (1) to develop, test, and

maintain a text message library, which addresses topics of HIV disease management, e.g. appointment keeping, retention in care, and medication adherence rates; and (2) to develop, implement, conduct, and evaluate a pilot study of delivering text messages to targeted youth receiving care at Ryan White grantee sites and other clinical sites.

The first phase of this project will include focus group interviews with the target audience to test the messages (Aim 1). Approximately 128 individuals will be screened to assess focus group eligibility. Four focus groups will be conducted with up to eight participants in each for a total sample size of 32.

The second phase of this project involves the evaluation of the pilot study (Aim 2). This will encompass data

collection with patients and providers. Patient participants for the pilot study will be recruited from ten clinical sites, some of which will be Ryan White grantees. Up to 1,000 individuals will be screened to determine eligibility for the pilot study to recruit a sample of 500 participants (50 from each clinical site). Patient participants will complete a baseline survey, 3-month survey, 6-month survey, and follow-up survey at 9 months. In addition, ten patient participants from each clinical site will be selected to participate in an in-depth, qualitative telephone interview for a total of 100 interviews. Finally, up to three clinic staff from the ten participating clinics will take part in in-depth, qualitative telephone interviews (N=30).

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Patient Focus Group Screener	128	1	128	0.25	32
Patient Focus Group Interview	32	1	32	2.0	64
Patient Pilot Study Screener	1000	1	1000	0.25	250
Patient Pilot Study Surveys	500	4	2000	0.75	1500
Patient Pilot Study Qualitative Interviews	100	1	100	1.0	100
Clinic Staff Pilot Study Qualitative Interviews	30	1	30	0.75	22.5
Total	1790	3290	1968.5

Dated: August 28, 2013.

Bahar Niakan,

Director, Division of Policy and Information Coordination.

[FR Doc. 2013–21557 Filed 9–4–13; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities; Proposed Collection; Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the

ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this Information Collection Request must be received within 60 days of this notice.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 10–29, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email paperwork@hrsa.gov or call the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: HRSA Telehealth Outcome Measures.

OMB No.: 0915–0311—Extension.

Abstract: To help carry out its mission, the Office for the Advancement of Telehealth (OAT) created a set of

performance measures that grantees can use to evaluate the effectiveness of their services programs and monitor their progress through the use of performance reporting data.

Need and Proposed Use of the Information: As required by the Government Performance and Review Act of 1993 (GPRA), all federal agencies must develop strategic plans describing their overall goal and objectives. The Office for the Advancement of Telehealth (OAT) has worked with its grantees to develop performance measures to be used to evaluate and monitor the progress of the grantees. Grantee goals are to: improve access to needed services; reduce rural practitioner isolation; improve health system productivity and efficiency; and improve patient outcomes. In each of these categories, specific indicators were designed to be reported through a performance monitoring Web site.

Likely Respondents: Telehealth Network Grantees.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to