determined by information indicating that the submission is written by an individual, for example, the comment is identified with the category ''Individual Consumer'' under the field titled ''Category (Required),'' on the ''Your Information'' page on *www.regulations.gov.* For this docket, however, FDA will not be following this general practice. Instead, FDA will post on *http://www.regulations.gov* comments to this docket that have been submitted by individuals in their individual capacity. If you wish to submit any information under a claim of confidentiality, please refer to 21 CFR 10.20.

*C. Information Identifying the Person Submitting the Comment*

Please note that your name, contact information, and other information identifying you will be posted on *http://www.regulations.gov* if you include that information in the body of your comments. For electronic comments submitted to *http://www.regulations.gov,* FDA will post the body of your comment on *http://www.regulations.gov* along with your state/province and country (if provided), the name of your representative (if any), and the category identifying you (*e.g.,* individual, consumer, academic, industry). For written submissions submitted to the Division of Dockets Management, FDA will post the body of your comments on *http://www.regulations.gov,* but you can put your name and/or contact information on a separate cover sheet and not in the body of your comments.

**IV. Electronic Access**

Persons with access to the Internet may obtain an electronic version of this guidance document at *http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm281147.htm* or *http://www.regulations.gov.*

Dated: September 16, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015–24218 Filed 9–23–15; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Meeting of the Secretary's Advisory Committee on Human Research Protections

**AGENCY:** Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** Pursuant to Section 10(a) of the Federal Advisory Committee Act, 5 U.S.C. App 2, notice is hereby given that the Secretary's Advisory Committee on Human Research Protections (SACHRP) will hold a meeting that will be open to the public. Information about SACHRP and the full meeting agenda will be posted on the SACHRP Web site at: *http://www.dhhs.gov/ohrp/sachrp/mtgings/index.html.*

**DATES:** The meeting will be held on Wednesday, October 21, 2015, from 8:30 a.m. until 5:00 p.m. and Thursday, October 22, 2015, from 8:30 a.m. until 4:30 p.m.

**ADDRESSES:** Fishers Lane Conference Center, Terrace Level, 5635 Fishers Lane, Rockville, Maryland 20852.

**FOR FURTHER INFORMATION CONTACT:** Jerry Menikoff, M.D., J.D., Director, Office for Human Research Protections (OHRP), or Julia Gorey, J.D., Executive Director, SACHRP; U.S. Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, Maryland 20852; telephone: 240–453–8141; fax: 240–453–6909; email address: *SACHRP@hhs.gov.*

**SUPPLEMENTARY INFORMATION:** Under the authority of 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, SACHRP was established to provide expert advice and recommendations to the Secretary of Health and Human Services, through the Assistant Secretary for Health, on issues and topics pertaining to or associated with the protection of human research subjects.

The meeting will open to the public at 8:30 a.m., on Wednesday, October 21, followed by opening remarks from Dr. Jerry Menikoff, Executive Secretary of SACHRP and OHRP Director, and Dr. Jeffrey Botkin, SACHRP Chair. The Committee will hear the Subpart A Subcommittee (SAS) and Subcommittee on Harmonization (SOH) reports on the recent Notice of Proposed Rulemaking (NPRM) titled Federal Policy for the Protection of Human Subjects (80 FR 53933, Sep. 8, 2015). Both days will be devoted to the discussion of the NPRM.

SAS was established by SACHRP in October 2006 and is charged with developing recommendations for consideration by SACHRP regarding the application of subpart A of 45 CFR part 46 in the current research environment.

SOH was established by SACHRP at its July 2009 meeting and charged with identifying and prioritizing areas in which regulations and/or guidelines for human subjects research adopted by various agencies or offices within HHS would benefit from harmonization, consistency, clarity, simplification and/or coordination.

The meeting will adjourn at 4:30 p.m. October 22, 2015. Time for public comment sessions will be allotted both days.

Public attendance at the meeting is limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify one of the designated SACHRP points of contact at the address/phone number listed above at least one week prior to the meeting. Pre-registration is required for participation in the on-site public comment session; individuals may pre-register the day of the meeting. Individuals who would like to submit written statements should email or fax their comments to SACHRP at *SACHRP@hhs.gov* at least five business days prior to the meeting.

Dated: September 18, 2015.

**Jerry Menikoff,**

*Executive Secretary, Secretary's Advisory Committee on Human Research Protections, Director, Office for Human Research Protections.*

[FR Doc. 2015–24264 Filed 9–23–15; 8:45 am]

**BILLING CODE 4150–36–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

### Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

**Project: Hospital Data Abstraction Form, Formerly Entitled Evaluation of Emergency Department Crisis Center Follow-Up—(OMB No. 0930–0337)—Revision**

The Substance Abuse and Mental Health Services Administration's (SAMHSA), Center for Mental Health Services (CMHS) will conduct an evaluation to assess the impact of crisis center follow-up with patients admitted to emergency departments following a suicide attempt.

The overarching purpose of the Hospital Data Abstraction Form, formerly entitled Evaluation of Emergency Department Crisis Center Follow-up, is to examine the impact of crisis center follow-up with patients admitted to emergency departments or inpatient behavioral health units following a suicide attempt or serious suicidal ideation on subsequent readmissions for suicidal behavior. This effort assesses the capacity of follow-up to save both lives and critical hospital resources. This evaluation effort includes one data collection activity. Clearance is being requested for the continuation and expansion of the already-approved abstraction form of hospital data on patients admitted to emergency departments or inpatient behavioral health units following a suicide attempt or serious ideation. This effort will continue to examine the impact of crisis center follow-up on readmissions for suicidal behavior. The data collected through this project will ultimately help SAMHSA to understand and direct crisis center follow-up lifesaving initiatives. The data collection activity is described below.

Hospitals collaborating with two cohorts (cohorts IV and V) of Lifeline crisis centers will participate in this expanded initiative. Fifteen hospitals per cohort will participate for a total of 30. Patient data will be collected for patients admitted for a suicide attempt in the two years prior to collaboration between the hospital and crisis center and for patients admitted for a suicide attempt for the two-year period after collaboration.

The Hospital Data Abstraction Form will be utilized to collect systematic patient data for patients seen in the 30 participating hospitals' emergency departments or inpatient behavioral health units. Information to be abstracted from patient data include: Demographic data, historical data, and subsequent suicidal behavioral and admission data. Data will be de-identified. Hospital staff will review patient data for qualifying (*i.e.,* admission to the emergency department for suicide attempt) records. Records to be reviewed will include emergency department or inpatient behavioral health unit admissions for the two years prior to crisis center and hospital collaboration and for two years following collaboration. It is expected that a total of 30,000 records will be abstracted by hospital staff and provided to the evaluation team.

This revision involves an increase in the number of participating hospital respondents and burden associated with the continuation/expansion of the already-approved Hospital Data Abstraction Form (OMB No. 0930–0337; Expiration 09/30/2016), as well as the discontinuation of data collection and burden associated with the Crisis Center Data Abstraction Form.

The estimated response burden to collect this information is as follows annualized over the requested three-year clearance period is presented below:

TOTAL AND ANNUALIZED AVERAGES: RESPONDENTS, RESPONSES, AND HOURS

| Instrument | Number of respondents | Responses per respondent * | Total number of responses | Burden per response | Annual burden * |
|---|---|---|---|---|---|
| Hospital Data Abstraction Form | 30 | 334 | 10,020 | .04 | 401 |

* Rounded to the nearest whole number

Written comments and recommendations concerning the proposed information collection should be sent by October 26, 2015 to the SAMHSA Desk Officer at the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). To ensure timely receipt of comments, and to avoid potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, commenters are encouraged to submit their comments to OMB via email to: *OIRA_Submission@omb.eop.gov*. Although commenters are encouraged to send their comments via email, commenters may also fax their comments to: 202–395–7285. Commenters may also mail them to: Office of Management and Budget, Office of Information and Regulatory Affairs, New Executive Office Building, Room 10102, Washington, DC 20503.

**Summer King,**

*Statistician.*

[FR Doc. 2015–24290 Filed 9–23–15; 8:45 am]

**BILLING CODE 4162–20–P**

## DEPARTMENT OF HOMELAND SECURITY

### U.S. Customs and Border Protection

### Accreditation and Approval of Amspec Services, LLC, as a Commercial Gauger and Laboratory

**AGENCY:** U.S. Customs and Border Protection, Department of Homeland Security.

**ACTION:** Notice of accreditation and approval of AmSpec Services, LLC, as a commercial gauger and laboratory.

**SUMMARY:** Notice is hereby given, pursuant to CBP regulations, that AmSpec Services, LLC, has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes for the next three years as of April 29, 2015.

**DATES:** *Effective Dates:* The accreditation and approval of AmSpec Services, LLC, as commercial gauger and laboratory became effective on April 29, 2015. The next triennial inspection date will be scheduled for April 2018.

**FOR FURTHER INFORMATION CONTACT:** Approved Gauger and Accredited Laboratories Manager, Laboratories and Scientific Services Directorate, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW., Suite 1500N, Washington, DC 20229, tel. 202–344–1060.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given pursuant to 19 CFR 151.12 and 19 CFR 151.13, that AmSpec Services, LLC, 100 Wheeler St., Unit G, New Haven, CT 06512, has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. AmSpec Services, LLC is approved for the following gauging procedures for petroleum and certain petroleum products from the American Petroleum Institute (API):

| API chapters | Title |
|---|---|
| 1 | Vocabulary. |
| 3 | Tank Gauging. |
| 7 | Temperature Determination. |
| 8 | Sampling. |
| 12 | Calculations. |