

Accreditation Criteria” provides information for those interested in participating in this voluntary program.

In the **Federal Register** of October 21, 2015 (80 FR 63806), 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 ¹

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Request for accreditation	1	1	1	80	80

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

Dated: April 12, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-1109]

Tobacco Farm Site Tours Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Center for Tobacco Products (CTP), is announcing an invitation for participation in its voluntary Tobacco Farm Site Tours Program. This program is intended to give CTP staff an opportunity to visit farms that grow tobacco for sale to tobacco product manufacturers in order to gain a better understanding of tobacco farming and the processes involved in curing and preparing tobacco intended for sale to tobacco product manufacturers. This program is not an FDA regulatory inspection, and tobacco farms are not regulated entities unless they are also a tobacco product manufacturer or controlled by a tobacco product manufacturer. The purpose of this notice is to invite parties interested in participating in the Tobacco Farm Site Tours Program to submit requests to CTP.

DATES: Submit either an electronic or written request for participation in this program by June 17, 2016. See section IV of this document for information on requests for participation.

ADDRESSES: If your farm is interested in offering a site visit, please submit a request either electronically to <http://www.regulations.gov> or in writing to the Division of Dockets Management (HFA-305), Food and Drug Administration,

5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Allison Hoffman, Office of Science, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 5426, Silver Spring, MD 20993-0002, 1-877-287-1373, email: CTPRegulations@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Pub. L. 111-31) into law, amending the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and giving FDA authority to regulate tobacco product manufacturing, distribution, and marketing.

CTP’s Office of Science is conducting the Tobacco Farm Site Tours Program to provide its staff an opportunity to visit farms that grow tobacco for sale to tobacco product manufacturers (a “tobacco product manufacturer” is defined as any person, including any repacker or relabeler, who manufactures, fabricates, assembles, processes, or labels a tobacco product, or imports a finished tobacco product for sale or distribution in the United States (section 900(20) of the FD&C Act (21 U.S.C. 387(20))). Although farms that grow tobacco are not FDA-regulated entities unless they are also a tobacco product manufacturer or controlled by a tobacco product manufacturer (see section 901(c)(2) of the FD&C Act (21 U.S.C. 387a(c)(2))), tobacco farm site visits will aid the Agency in gaining a better understanding of tobacco farming and the processes involved in curing and preparing tobacco leaf intended for sale to tobacco product manufacturers. The goal for the Tobacco Farm Site Tours Program is for CTP staff to gain firsthand exposure to tobacco farming practices, including cultivation, harvesting, curing, and preparation for sale of tobacco leaf to tobacco product manufacturers.

II. Description of Tobacco Farm Site Tours Program

In the Tobacco Farm Site Tours Program, small groups of CTP staff plan to observe the operations of farms that grow tobacco for sale to tobacco product manufacturers. Please note that FDA does not regulate these farms and the Tobacco Farm Site Tours Program is not an inspection of facilities to determine compliance with the FD&C Act; rather, this program is meant to educate CTP staff and improve their understanding of tobacco farming. It is anticipated that the tobacco farm site tours will take place in the fall of 2016.

III. Site Selection

CTP hopes to be able to tour small, medium, and large farms, and farms that grow tobacco for different kinds of tobacco products. Final site selections will be based on the availability of funds and resources for the relevant fiscal year as well as the desire to visit a wide variety of types of tobacco farms. FDA plans on visiting nine or fewer farms. All FDA travel expenses associated with the farm site tours will be the responsibility of FDA.

IV. Requests for Participation

To aid in site selection, your request for participation should include the following information:

- A description of your farm, including the size of the farm;
- A list of the type(s) of tobacco grown and the kinds of tobacco product manufacturers to whom you sell tobacco;
- The physical address(es) of the site(s) for which you are submitting a request; and
- A proposed 1-day tour agenda.

Identify requests for participation with the docket number found in brackets in the heading of this document. Received requests are available for public examination in the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 12, 2016.
Leslie Kux,
Associate Commissioner for Policy.
 [FR Doc. 2016-08900 Filed 4-15-16; 8:45 am]
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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 no later than June 17, 2016.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA

Information Collection Clearance Officer, Room 14N-39, Parklawn Building, 5600 Fishers Lane, Rockville, MD 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: Black Lung Clinics Program Performance Measures

OMB No. 0915-0292—Extension.
 Abstract: The Federal Office of Rural Health Policy (FORHP), HRSA, conducts an annual data collection of user information for the Black Lung Clinics Program, which has been ongoing with OMB approval since 2004. The purpose of the Black Lung Clinics Program is to reduce the morbidity and mortality associated with occupationally related coal mine dust lung disease through the screening, diagnosis, and treatment of active, inactive, retired, and/or disabled coal miners. Collecting this data provides HRSA with information on how well each grantee is meeting the needs of these miners in their communities.

Need and Proposed Use of the Information: Data from the annual report provides quantitative information

about the clinics, specifically: (a) The characteristics of the patients they serve (gender, age, disability level, occupation type); (b) the characteristics of services provided (medical encounters, non-medical encounters, benefits counseling, and outreach); and, (c) the number of patients served. This assessment enables HRSA to provide data required by Congress under the Government Performance and Results Act of 1993. It also ensures that funds are effectively used to provide services that meet the target population needs. HRSA does not plan to make any changes to the performance measures at this time.

Likely Respondents: Black Lung Clinics Program 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 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 Information Collection Request 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
Black Lung Clinics Program Measures	15	1	15	10	150
Total	15	1	15	10	150

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information

technology to minimize the information collection burden.

Jackie Painter,
Director, Division of the Executive Secretariat.
 [FR Doc. 2016-08802 Filed 4-15-16; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C.,