

and will select and notify participants by September 14, 2016. All requests to make oral presentations must be received by September 13, 2016. If selected for presentation, any presentation materials must be emailed to David Litwack (see **FOR FURTHER INFORMATION CONTACT**) no later than September 16, 2016, at 5 p.m. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

FDA is holding this public workshop to obtain feedback on its recently released draft guidance documents: "Use of Public Human Genetic Variant Databases to Support Clinical Validity for Next Generation Sequencing-Based In Vitro Diagnostics" and "Use of Standards in the Food and Drug Administration's Regulatory Oversight of Next Generation Sequencing-Based In Vitro Diagnostics Used for Diagnosing Germline Diseases". In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the public workshop topics. The deadline for submitting comments related to this public workshop is October 6, 2016.

*Transcripts:* Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (see **ADDRESSES**). A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency's Web site at <http://www.fda.gov>. A link to the transcripts will also be available approximately 45 days after the public workshop on the Internet at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. (Select this public workshop from the posted events list.)

Dated: August 17, 2016.

**Peter Lurie,**

*Associate Commissioner for Public Health Strategy and Analysis.*

[FR Doc. 2016-19939 Filed 8-19-16; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2016-N-0001]

#### National Mammography Quality Assurance Advisory Committee; Amendment of Notice

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the National Mammography Quality Assurance Advisory Committee. This meeting was announced in the **Federal Register** of August 5, 2016. The amendment is being made to reflect a change in the **ADDRESSES** portion of the document. There are no other changes.

**FOR FURTHER INFORMATION CONTACT:** S.J. Anderson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1552, Silver Spring, MD 20993-0002, [Sara.Anderson@fda.hhs.gov](mailto:Sara.Anderson@fda.hhs.gov), 301-796-6875, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code MA. Please call the Information Line for up-to-date information on this meeting.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of August 5, 2016 (81 FR 51918), FDA announced that a meeting of the National Mammography Quality Assurance Advisory Committee would be held on September 15, 2016. On page 51919, in the first column, in the **ADDRESSES** portion: Hilton Washington, DC/North, Salons A, B, C and D, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's telephone number is 301-977-8900, is changed to read as follows: Gaithersburg Holiday Inn—Grand Ballroom, 2 Montgomery Village Ave., Gaithersburg, MD 20878. The hotel's telephone number is 301-948-8900.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: August 17, 2016.

**Janice M. Soreth,**

*Acting Associate Commissioner, Special Medical Programs.*

[FR Doc. 2016-19957 Filed 8-19-16; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2016-N-2474]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Reporting Associated With Designated New Animal Drugs for Minor Use and Minor Species

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the reporting associated with designation under the Minor Use and Minor Species Animal Health Act of 2004.

**DATES:** Submit either electronic or written comments on the collection of information by October 21, 2016.

**ADDRESSES:** You may submit comments as follows:

#### *Electronic Submissions*

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the

public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

*Instructions:* All submissions received must include the Docket No. FDA-2016-N-2474 for “Reporting Associated with Designated New Animal Drugs for Minor Use and Minor Species.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/>

[regulations.gov/dockets/default.htm](http://www.regulations.gov/dockets/default.htm).

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

#### **Reporting Associated With Designated New Animal Drugs for Minor Use and Minor Species; 21 CFR Part 516 OMB Control Number 0910–0605—Extension**

The Minor Use and Minor Species (MUMS) Animal Health Act of 2004 (Pub. L. 108–282) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to authorize FDA to establish new regulatory procedures intended to make more medications legally available to veterinarians and animal owners for the treatment of minor animal species as well as uncommon diseases in major animal species. This legislation provides incentives designed to help pharmaceutical companies overcome the financial burdens they face in providing limited-demand animal drugs. These incentives are only available to sponsors whose drugs are “MUMS-designated” by FDA. Minor use drugs are drugs for use in major species (cattle, horses, swine, chickens, turkeys, dogs, and cats) that are needed for diseases that occur in only a small number of animals either because they occur infrequently or in limited geographic areas. Minor species are all animals other than the major species; for example, zoo animals, ornamental fish, parrots, ferrets, and guinea pigs. Some animals of agricultural importance are also minor species. These include animals such as sheep, goats, catfish, and honeybees. Participation in the MUMS program is completely optional for drug sponsors so the associated reporting only applies to those sponsors who request and are subsequently granted “MUMS designation.”

Our regulations in 21 CFR part 516 specify the criteria and procedures for requesting MUMS designation as well as the annual reporting requirements for MUMS designees. Section 516.20 provides requirements on the content and format of a request for MUMS-drug designation; § 516.26 provides requirements for amending MUMS-drug designation; § 516.27 provides for change in sponsorship of MUMS-drug designation; § 516.29 provides for termination of MUMS-drug designation; § 516.30 contains the requirements for annual reports from sponsor(s) of MUMS-designated drugs; and § 516.36 sets forth consequences for insufficient quantities of MUMS-designated drugs.

*Description of Respondents:* The respondents to this information collection are pharmaceutical companies that sponsor new animal drugs.

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

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

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
516.20; content and format of MUMS request .....	15	5	75	16	1200
516.26; requirements for amending MUMS designation .....	3	1	3	2	6
516.27; change in sponsorship .....	1	1	1	1	1
516.29; termination of MUMS designation .....	2	1	2	1	2
516.30; requirements of annual reports .....	15	5	75	2	150
516.36; insufficient quantities .....	1	1	1	3	3
<b>Total</b> .....					<b>1,362</b>

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

The burden estimate for this reporting requirement was derived in our Office of Minor Use and Minor Species Animal Drug Development by extrapolating the investigational new animal drug/new animal drug application reporting requirements for similar actions by this same segment of the regulated industry and from previous interactions with the minor use/minor species community.

Dated: August 16, 2016.

**Jeremy Sharp,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

[FR Doc. 2016–19919 Filed 8–19–16; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Proposed Changes to the Black Lung Clinics Program

**AGENCY:** Health Resources and Services Administration (HRSA), HHS.

**ACTION:** Request for Public Comment on Proposed Changes to the Black Lung Clinics Program for Consideration for the FY 2017 Funding Opportunity Announcement Development.

**SUMMARY:** This notice seeks comments on a range of issues pertaining to the Black Lung Clinics Program (BLCP), which will be competitive in Fiscal Year (FY) 2017. HRSA's Federal Office of Rural Health Policy allocates funds for state, public, or private entities that provide medical, educational, and outreach services to active, inactive, and retired coal miners with disabilities. Funding allocations take into account the number of miners to be served; their medical, outreach, and educational needs; and the quality and breadth of services that are provided. HRSA requests feedback on how to best determine the needs of coal miners and

their families, given the available data, and how to better equip future BLCP grantees to meet those needs.

**DATES:** Submit written comments no later than September 21, 2016.

**ADDRESSES:** Written comments should be submitted to [Blacklung@hrsa.gov](mailto:Blacklung@hrsa.gov).

#### FOR FURTHER INFORMATION CONTACT:

Allison Hutchings, Program Coordinator, Black Lung Clinics Program, Federal Office of Rural Health Policy, Health Resources and Services Administration, [Blacklung@hrsa.gov](mailto:Blacklung@hrsa.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

##### a. Authorizing Legislation and Program Regulations

BLCP is authorized by Section 427(a) of the Federal Mine Safety and Health Act of 1977 (30 U.S.C. 937(a)), as amended, and accompanying regulations found at 42 CFR part 55a ("BLCP regulations"). HRSA began administering the program in FY 1979, when \$7.5 million was appropriated. HRSA awarded approximately \$6.5 million to clinics in FY 2015.

The primary goal of the BLCP is to reduce the morbidity and mortality associated with occupationally-related coal mine dust lung disease. The BLCP regulations (42 CFR part 55a) state that BLCP grantees must provide for the following services to active and inactive miners, in consultation with a physician with special training or experience in the diagnosis and treatment of respiratory diseases: primary care; patient and family education and counseling; outreach; patient care coordination; antismoking advice; and other symptomatic treatments. Additionally, BLCP grantees must serve as payers of last resort and be able to administer, or provide referrals for, U.S. Department of Labor (DOL) disability examinations.

##### b. Eligibility and Funding Criteria

The BLCP funding opportunity is open to any state or public or private entity that meets the requirements of the BLCP as described above. These entities include faith-based and community-based organizations, as well as federally recognized Tribes and Tribal organizations.

The BLCP regulations state that the funding criteria for applicants should take into account: (1) *The number of miners to be served and their needs;* and (2) *the quality and breadth of services to be provided.* The regulations also state that "the Secretary will give preference to a State, which meets the requirement of this part and applies for a grant under this part, over other applications in that State".

##### c. Application Cycle

HRSA administers the BLCP over 3-year grant cycles. The program was last competitive in FY 2014, and current BLCP grantees finished their second year of the cycle on June 30, 2016. The program will be competitive again in FY 2017.

## II. Current Challenges

##### a. Growing Need for Black Lung Services

In FY 2000, surveillance data from the Centers for Disease Control and Prevention's National Institute of Occupational Safety and Health (NIOSH) showed an unexpected increase in the national prevalence of coal workers' pneumoconiosis (CWP), also known as black lung disease, after nearly three decades of steady decline following the enactment of the Federal Coal Mine Health and Safety Act of 1969. The overall CWP prevalence among U.S. coal workers declined from 11 percent in 1970 to 2 percent in 1999. However, since 2000, the prevalence of CWP has increased to 3 percent and continues to rise. According to NIOSH surveillance data, the rise in CWP has been the most severe among coal miners