SUPPORTING STATEMENT FOR INFORMATION COLLECTION

UNITED STATES DEPARTMENT OF AGRICULTURE (USDA)

ANIMAL AND PLANT HEALTH INSPECTION SERVICE (APHIS)

VETERINARY SERVICES (VS)

CENTERS FOR EPIDEMIOLOGY AND ANIMAL HEALTH (CEAH),

NATIONAL ANIMAL HEALTH MONITORING SYSTEM (NAHMS)

NAHMS ANTIMICROBIAL USAGE STUDY
Part A

SUPPORTING STATEMENT FOR INFORMATION COLLECTION BY THE CENTER FOR EPIDEMIOLOGY AND ANIMAL HEALTH (CEAH), NATIONAL ANIMAL HEALTH MONITORING SYSTEM (NAHMS)
OMB NUMBER 0579-XXXX
NAHMS Antimicrobial Usage Study

February 2017

A. Justification

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection. Attach a copy of the pertinent section of each statute and regulation mandating or authorizing the collection of information.

This submission is a request for approval to initiate the National Animal Health Monitoring System's (NAHMS') Antimicrobial Usage Study, an information collection by the Animal and Plant Health Inspection Service (APHIS.

This study will consist of two surveys, a swine survey and a feedlot survey. For swine, selected operations in 13 States[1] with 1000 or more nursery pigs or grower-finisher pigs will be eligible for participation. For feedlots, there will be 2 components: the large component will include all operations with 1,000 or more head capacity in 16 States[2]; and the small component will include selected operations with 50-999 head capacity in 13 States[3].

This collection from both commodities will support the following general objectives:

1) Describe antimicrobial usage in weaned market hogs (nursery and grower/finisher ages) to control and treat disease and promote growth on a regional and national basis both before and after implementation of changes in FDA's Veterinary Feed Directive (VFD)[4]. Usage will be measured by the percent of operations that administer antimicrobials and the percent of animals that receive antimicrobials.

2) Provide this information to the U.S. Swine and Feedlot industries as well as legislators to help form policy based on objective estimates.

3) Use findings from the study as a basis for more in-depth evaluation of usage and resistance in a subsequent longitudinal study on farms.

---

[1] Colorado, Illinois, Indiana, Iowa, Kansas, Minnesota, Missouri, Nebraska, North Carolina, Ohio, Oklahoma, Pennsylvania, and South Dakota.

[2] Arizona, California, Colorado, Idaho, Illinois, Iowa, Kansas, Minnesota, Nebraska, New Mexico, Oklahoma, Oregon, South Dakota, Texas, Washington, and Wyoming.

[3] Colorado, Illinois, Indiana, Iowa, Kansas, Michigan, Minnesota, Missouri, Nebraska, Ohio, Pennsylvania, South Dakota, and Wisconsin.

[4] http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm071807.htm

The information collected through the Antimicrobial Usage Study will be analyzed and organized into one or more descriptive reports. Information sheets highlighting topics of special interest may be derived from the reports and disseminated by APHIS to producers, stakeholders, academicians, veterinarians, and any other interested parties. The benefits to the Swine and Feedlot industries from the Antimicrobial Usage Study include scientifically valid national estimates of antimicrobial use by Swine and Feedlot producers. Participation in this survey is voluntary. Producers will choose whether to participate.

Collection and dissemination of animal health data and information is mandated by 7 U.S.C. § 391, the Animal Industry Act of 1884, which established the precursor of the APHIS, Veterinary Services, the Bureau of Animal Industry. Legal requirements for examining and reporting on animal disease control methods were further mandated by 7 U.S.C. § 8308 of the Animal Health Protection Act, "Detection, Control, and Eradication of Diseases and Pests," May 13, 2002.

Collection, analysis, and dissemination of livestock and poultry health information on a national basis are consistent with the APHIS mission of protecting and improving American agriculture's productivity and competitiveness. In connection with this mission, the NAHMS program includes periodic national commodity studies to investigate current issues and examine general health and management practices used on farms. These studies are driven by industry and stakeholder interest. The information collected is not available from any other source.

2. Indicate how, by whom, how frequently, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection.

Statistically summarized information and interpretation will be disseminated to a wide variety of constituents. Producer groups and veterinarians will use information derived from analyses for information outreach efforts to legislators and the public. Pharmaceutical and biologics companies will use the information to plan and develop research and marketing strategies for their products. State and Federal officials responsible for regulatory veterinary medicine will use the information to gain a more complete picture of antimicrobial use to use as a basis for program planning and to direct funding. State and Federal officials will also use the data so that scientifically based information is used to make decisions. Veterinary and agricultural students in universities in the U.S. will use the reports for training in health management, animal welfare and other agriculturally based careers.

The Antimicrobial Usage Study will be the first NAHMS study designed to focus exclusively on this topic. As such, the Antimicrobial Usage Study is designed to establish statistically valid regional and national estimates. This information will provide important reference information that will enable the evaluation of trends in antimicrobial usage in the swine and feedlot industries through future annual studies. Finally, this information will provide stakeholders with usage estimates before and after the varying stages of the implementation of changes in the VFD.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and

the basis for the decision for adopting this means of collection. Also describe any consideration of using information technology to reduce burden.

Electronic technologies will be used to help promote the Antimicrobial Usage Study. Producers will learn about the Antimicrobial Usage Study via paper or internet mailings via association membership lists, notices posted on industry Web sites, or notices published in trade magazines or other agricultural publications. The primary data collection instrument will be a hard-copy questionnaire.

4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purpose described in item 2 above.

Literature searches for existing data relevant to the Antimicrobial Usage Study have been performed. Available data were reviewed and compiled from all known sources. Sources reviewed include private industry and professional publications, other Federal and State agencies, and universities. Employees from Federal agencies and academia were consulted in their area of expertise to identify areas of potential duplication. Previous NAHMS Swine and Feedlot studies have been used to create the questions in the surveys. Retrospective studies of previous NAHMS swine and feedlot studies as they pertain to the subject matter of the current study are ongoing. The retrospective analyses are to provide background for the current one and evaluate historical antimicrobial resistance. However, it should be noted that these studies were not designed specifically to collect use information and the data are not current. No other entity/source is collecting and analyzing this type of information to obtain national or regional estimates.

5. If the collection of information impacts small businesses or other small entities, describe any methods used to minimize burden. Include the percentage of respondents contacted that are small entities.

The Antimicrobial Usage Study is designed to collect data from sampled producers who are willing to participate. For the swine survey, the target population is limited to large producers with 1,000 or more nursery or grower/finisher pigs. Estimates of the number of respondents, based on the population of feedlot and swine producers, indicate that the proposed sample size will be sufficient to meet the primary analytical needs of the study (see Part B for more details).. Producers who choose to participate will be able to complete the questionnaire when it is most convenient for them from 3 July to 11 August 2017, which will minimize potential impacts on business operations. Industry and producer input into the questionnaire was solicited to ensure that information collected is relevant and timely. This is a voluntary program. The individual producer will choose whether to participate.

6. Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.

Previous NAHMS commodity studies have described some antimicrobial use on a national level. However, we have never designed a study to solely collect this information. In addition this is a pivotal time as existing practices are in flux due to existing and upcoming changes in the VFD.

Estimates of antimicrobial use before and after implementation of new VFD regulations are important to assess for two reasons. One is to assess how producers have adjusted their practices to comply with the new VFD. The second is to describe use before and after the change. For example, we wish not only to provide a national estimate of the percent of sites that use X antibiotic in nursery pigs feed for growth promotion before and after the new VFD.

Without this type of national data, the United States will have no ability to understand and develop information on trends in antimicrobial use. The United States would not be able to provide objective information evaluate the results of the FDA's decision.

7. Explain any special circumstances that require the collection to be conducted in a manner inconsistent with the general information collection guidelines in 5 CFR 1320.5.

- **requiring respondents to report information to the agency more often than quarterly;**
- **requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;**
- **requiring respondents to submit more than an original and two copies of any document;**
- **requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;**
- **in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;**
- **requiring the use of a statistical data classification that has not been reviewed and approved by OMB;**
- **that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or**
- **requiring respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.**

Due to NASS printing workloads and timelines and with prior OMB approval, copies of questionnaires may be sent to potential study participants by NASS in May 2017 without an OMB control number. APHIS will perform the actual data collection from consenting individuals in June 2017. This additional time will ensure that these additional copies will have the OMB control number printed on the form for the data collection.

8. Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and record keeping, disclosure, or reporting form, and on the data elements to be recorded, disclosed, or reported. If applicable, provide a copy and identify the date and page number of

publication in the Federal Register of the agency's notice, soliciting comments on the information collection prior to submission to OMB.

The following people were consulted during planning and development of the Antimicrobial Usage Study:

Dr. Liz Wagstrom, National Pork Producer's Council, Chief Veterinarian National Pork Board, 122 C Street N.W. Suite 875 Washington D.C. 20001. (202) 347-3600.

Dr. Harry Snelson, Director of Communications for the American Association of Swine Veterinarians, 830 26th Street Perry, IA 50220 (515) 465-5255.

Dr. Jennifer Koeman Director of Producer and Public Health, Science & Technology, National Pork Board, 1776 NW 114th Street, Des Moines, Iowa 50325 (515) 223-2600.

Dr. Peter Davies, Professor, Veterinary Population Medicine, University of Minnesota Twin Cities, 225 Veterinary Medical Center, 1365 Gortner Avenue, University of Minnesota St. Paul, MN 55108 (612) 625-8290.

Dr. Mike Apley, Clinical Sciences, College of Veterinary Medicine, Kansas State University, A-111 Mosier Hall, Manhattan, KS 66506 (785) 532-4890

Dr. Kathy Simmons, National Cattlemen's Beef Association, 1301 Pennsylvania Ave NW, Ste 300NW, Washington, DC 20004 ksimmons@beef.org

Dr. Gatz Riddell, American Association of Bovine Practitioners, PO Box 3610, Auburn, AL 36831 mgriddell@aabp.org

Dr. Thomas Portillo, Friona Industries, 500 S Taylor St., PO Box 15568, Amarillo, TX taportillodvm@gmail.com

Dr. John Davidson, Boehringer Ingelheim Vetmedica Inc , P.O. Box 1600, Shiner, TX john.davidson@boehringer-ingelheim.com

9. Explain any decision to provide any payment or gift to respondents, other than reenumeration of contractors or grantees.

There will be no payments or gifts provided to respondents.

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy.

On March 20, 2012, NAHMS was recognized by OMB as a statistical unit under Title V of the E-Government Act of 2002, Public Law 107-347, Section 513 (the Confidential Information Protection and Statistical Efficiency Act of 2002 [CIPSEA]). All information acquired from respondents under the Antimicrobial Usage Study will be used for statistical purposes only and will be treated as confidential in accordance with CIPSEA guidelines. Only NAHMS staff and designated agents will be permitted access to individual-level data.

Hard-copy questionnaires and data will refer to the respondent by a numeric code. The link between participants' PII and numeric code will only be known to NASS (who will select the sample) and to APHIS field staff (who will collect the data). Survey forms will not have any PII. The link between PII and survey data will be destroyed once data collection, entry, validation, and report dissemination are complete. All completed survey forms will be stored securely in a limited-access records room. Therefore, no connection can be made between a completed questionnaire and a specific respondent. Only summary estimates will be reported.

NASS has statutory protection that allows the agency to keep on-farm data (such as producer name and address information) confidential. Several U.S. Codes apply to data collected by NASS:

- Title 7, Section 2276 - Confidentiality of Information.
- Title 18, Section 1902 - Disclosure of Crop Information and Speculation Thereon.
- Title 18, Section 1905 - Disclosure of Confidential Information Generally.

NAHMS has statutory protection that allows for the protection of respondent data through the Confidential Information Protection and Statistical Efficiency Act (CIPSEA):

- Title V of E-Government Act of 2002, Public Law 107-347, Section 513. Fines and Penalties.
- Title V of E-Government Act of 2002, Public Law 107-347, Section 512. Limitations on Use and Disclosure of Data and Information.

Every individual that may handle a questionnaire, or data coming from a completed questionnaire, is required to sign a form governing Certification and Restrictions on use of Unpublished Data. Furthermore, once data are published, individuals are generally limited to the use of aggregate data files. Access to individual data files is restricted to maintain respondent confidentiality.

Several additional U.S. Codes apply to data collected by NAHMS:

- Title 7, Section 2276 - Confidentiality of Information.
- Title 18, Section 1902 - Disclosure of Crop Information and Speculation Thereon.
- Title 18, Section 1905 - Disclosure of Confidential Information Generally.
- Section 1619 of the 2008 Farm Bill

Respondents will be given the following confidentiality pledge:

Background

USDA's Animal and Plant Health Inspection Service (APHIS) is collecting information on antimicrobial use through the National Animal Monitoring System (NAHMS). This information will be used to describe current antimicrobial use practices, help policymakers and industry make informed decisions, assist researchers and private enterprise in identifying and focusing on vital issues related to antimicrobial use, and facilitate education of future producers and veterinarians.

Participation is voluntary and you may decline to participate. Your participation is vital and will help develop national estimates of antimicrobial use practices. We ask that you provide accurate information regarding your operation's antimicrobial use practices; however, you retain the right to refuse to answer any or all questions.

Confidentiality

The information you, or your establishment, provide to the data collector will be used for statistical purposes only. In accordance with the Confidential Information Protection provisions of Title V, Subtitle A, Public Law 107-347 and other applicable Federal laws, your responses will be kept confidential and will not be disclosed in identifiable form. Only authorized APHIS employees or those acting on APHIS's behalf (NAHMS agents), who are subject to fines and imprisonment for unauthorized disclosure, will have access to your individual record data. By law to be an authorized APHIS employee or NAHMS agent, individuals must take an oath which states that no confidential information will be released, and that the individual is subject to a jail term of up to 5 years, a fine of up to $250,000, or both if he or she discloses ANY identifiable information about you or your establishment.

Your data's security is vitally important to APHIS. Every person working for or in cooperation with APHIS on this study has signed a confidentiality form which stipulates the requirements for keeping data confidential and the penalties individuals are subject to if identifiable information is released. Further, data are protected from cybersecurity threats. Under the Cybersecurity Enhancement Act of 2015, your data will be protected by US Department of Homeland Security (DHS) cybersecurity monitoring. In the event of a cybersecurity incident, and pursuant to any required legal processes, information from these sources may be used to help identify and mitigate the incident

APHIS may publish, or authorize others to publish, the aggregate (summary) findings acquired from NAHMS for the benefit of the swine and beef industries, allied private industries, and other interested groups, but will ensure that the identity of the producer is withheld. APHIS may not publish, or authorize others to publish, individual responses.

Please note that information on a producer's animals revealed from sources unrelated to this antimicrobial use study, such as testing and inspection for movement or sale of animals or tracebacks on testing done at slaughter, may cause unrelated regulatory action.

You can obtain these reports and further information from this study by accessing the NAHMS Web site at: https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/monitoring-andsurveillance/nahms/ct_national_animal_health_monitoring_system_nahms_home

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior or attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

There are no questions of a sensitive nature used in this collection activity.

12. Provide estimates of the hour burden of the collection of information. Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated.

- **Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens in Item 13 of 0MB Form 83-I.**

  A total of 6716 annual burden hours are needed to complete the Antimicrobial Usage Study over the collection period for this information collection. A detailed burden estimate has been included on the enclosed APHIS 71 Form.

- **Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using the correct wage rate categories.**

  Respondent costs: Estimated respondent costs for the information collection proposed are calculated based on a data collection estimate of $13.25[1] per hour. The total respondent cost for Antimicrobial Usage Study is $88,987 (6,716 hours x $13.25).

13. Provide estimates of the total annual cost burden to respondents or record keepers resulting from the collection of information (do not include the cost of any hour burden shown in items 12 and 14). The cost estimates should be split into two components: (a) a total capital and startup cost component annualized over its expected useful life; and (b) a total operation and maintenance and purchase of services component.

There are no capital/start-up costs or ongoing operations and maintenance costs associated with this information collection.

14. Provide estimates of annualized cost to the Federal government. Provide a description of the method used to estimate cost and any other expense that would not have been incurred without this collection of information.

The estimated cost to the Federal Government to administer the Antimicrobial Usage study is $2,001,988. For more specific information, please see the enclosed APHIS 79 form.

15. Explain the reasons for any program changes or adjustments reported in Items 13 or 14 of the OMB Form 83-1.

This is a new information collection to examine antimicrobial use.

16. For collections of information whose results are planned to be published, outline plans for tabulation and publication.

Information from this survey will be summarized immediately following the collection, validation and editing of the data. Data will be entered into a database management system, and statistical calculations will be performed, e.g., descriptive statistics including frequency distribution, prevalence, and ratio estimates. Variance measures and confidence intervals for the point estimates will be calculated in order to describe the precision of the descriptive statistics generated. SUDAAN software from RTI will be used to correctly calculate the standard error to account for the study design. Standard errors will be published along with the point estimates.

[1] NASS Farm Labor, published report for October 2016, released November, 2016: http://usda.mannlib.cornell.edu/usda/current/FarmLabo/FarmLabo-11-17-2016.pdf

Efforts are made to reduce the time between the end of data collection and release of a final publication. Hardcopy and electronic information from the study will be made available to producers, universities, researchers, practitioners, animal health related industries, Federal agencies, legislators, and any other interested party. Any published summary data will be available by following the "Antimicrobial Resistance" link at http://www.aphis.usda.gov/nahms.

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.

APHIS is not seeking an exemption to display the expiration date for OMB approval.

18. Explain each exception to the certification statement identified in the "Certification for Paperwork Reduction Act."

APHIS is able to certify compliance with all provisions in the Paperwork Reduction Act.