SUPPORTING STATEMENT FOR INFORMATION COLLECTION Part A

UNITED STATES DEPARTMENT OF AGRICULTURE (USDA) ANIMAL AND PLANT HEALTH INSPECTION SERVICE (APHIS) VETERINARY SERVICES (VS) THE CENTERS FOR EPIDEMIOLOGY AND ANIMAL HEALTH (CEAH), NATIONAL CENTER FOR ANIMAL HEALTH SURVEILLANCE (NCAHS)

NAHMS DAIRY 2007

SUPPORTING STATEMENT FOR INFORMATION COLLECTION BY THE CENTERS FOR EPIDEMIOLOGY AND ANIMAL HEALTH (CEAH), NATIONAL CENTER FOR ANIMAL HEALTH SURVEILLANCE (NCAHS)¹ OMB NUMBER 0579-0205 NAHMS DAIRY 2007 STUDY

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A. JUSTIFICATION

This submission is a request for approval to initiate the National Animal Health Monitoring System's (NAHMS') Dairy 2007 study, an information collection by the Animal and Plant Health Inspection Service (APHIS). The study will consist of 2 phases. In phase I (NASS phase), a NASS enumerator will contact and conduct interviews with producers (NAHMS-187 General Dairy Management Report Questionnaire). In the top 17 dairy producing states²., if the respondent has 30 or more milk cows, they will be asked to sign a consent form allowing NASS to present their names to APHIS designated data collectors for further consideration in the study. Phase II (APHIS phase) will consist of completing the producer agreement and two on-farm questionnaires. In addition, biologic sampling will be available to all participants that complete an on-farm questionnaire and have 30 or more [head of] milk cows. The first study questionnaire will be administered by National Agricultural Statistics Service (NASS) and follow-up questions and biologic collection administered by APHIS designated data collectors. The collection will support the following objectives:

1) Describe trends in dairy cattle health and management practices

2) Evaluate management factors related to cow comfort and removal rates

3) Describe dairy calf health and nutrition from birth to weaning and evaluate heifer disease prevention practices

4) Estimate the prevalence of herds infected with bovine viral diarrhea virus (BVD)

5) Describe current milking procedures and estimate the prevalence of contagious mastitis pathogens

6) Estimate the herd-level prevalence and associated costs of *Mycobacterium paratuberculosis*

¹ The National Center for Animal Health Surveillance is responsible for collecting national data on animal health and productivity from voluntary participants

² California, Idaho, Indiana, Iowa, Kentucky, Michigan, Minnesota, Missouri, New Mexico, New York, Ohio, Pennsylvania, Texas, Vermont, Virginia, Washington, Wisconsin.

7) Describe current biosecurity practices and determine producer motivation for implementing or not implementing proper biosecurity practices

8) Determine the prevalence of specific food safety pathogens and describe antimicrobial resistance patterns

The information collected through the Dairy 2007 study will be analyzed and organized into descriptive reports. Several information sheets will be derived from this report and be disseminated by APHIS to producers, stakeholders, academia, veterinarians, and any other interested parties. One of the reports will present change over time from previous NAHMS Dairy studies. Participation in this survey is voluntary; it is up to the individual producer to decide whether or not it is desirable to participate.

1. Explain why the collection of this information is necessary.

Collection and dissemination of animal health data and information is mandated by 7 U.S.C. § 391, the Animal Industry Act of 1884³, which established the precursor of the APHIS, Veterinary Services, and 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, 2002³.

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 animal health related issues and examine general health and management practices used on farms. These studies are driven by industry and stakeholder interest, and will collect information that is not available from any other source. Without this study, APHIS would be unable to continue the trends analysis that began with The Dairy Heifer Evaluation Project in 1991-92 that various parts of the industry as well as many federal and state partners have come to rely on.

NAHMS will initiate the fourth national data collection for dairy through Dairy 2007. NAHMS staff has completed a needs assessment which was a collaborative effort with producers, industry, extension specialists, Federal and State personnel, and university researchers. Information gathered through this needs assessment was used to determine the study objectives.

National Surveys Providing Baseline Information

The Dairy 2007 study is part of an ongoing series of NAHMS studies on the U.S. dairy population. The first NAHMS dairy study, which provided a dairy health and management baseline, was conducted in 1991. The National Dairy Heifer Evaluation Project (NDHEP), 1991-92, provided an overview of dairy herd management practices, morbidity and mortality concentrating on the preweaned heifer. The objectives of the study were to provide information on the production and health levels of the United States' dairy herd, and to suggest factors that

³ 7 United States Code § 391, and 7 U.S.C. § 8308, are attached in the Background Information section (section 6).

may affect morbidity, and mortality in preweaned heifers. Subsequent studies, focusing on all ages of animals, were performed in 1996 and 2002.

Dairy 1996: NAHMS' second national on-farm monitoring activity. Data were collected from operations in 20 of the largest dairy-producing states. Dairy '96 obtained baseline information on all phases of dairy production and management. The sub-sampling phase of Dairy '96 collected fecal and blood samples which were tested for the presence of *Mycobacterium avium* subspecies *paratuberculosis*, *Salmonella*, *Escherichia coli*, and other dairy pathogens which have an economic impact on dairy operations.

Dairy 2002 gathered information that described changes in management practices and animal health in dairy operations from 1991-92 and 1996 to 2002. Data were collected from operations in 21 states to describe management practices on dairy operations. Dairy 2002 also identified factors associated with shedding of specific pathogens, described antimicrobial usage, and described animal health management practices and their relationships to dairy health. Approximately 85 percent of the U.S. milk cow inventory and 83% of U.S. dairy operations were represented in the study.

2. Indicate how, by whom, and for what purpose the information is to be used. Indicate the actual use the Agency has made of the information received from the current collection._

Data collected, analyzed, and interpreted is disseminated to a wide variety of constituents⁴. Producers will use the information to compare their operation's animal health and productivity with other herds regionally and nationally. Producer groups and veterinarians will use information derived from analyses to improve preventive measures and information outreach efforts. Pharmaceutical and biologics companies will use the information to plan and develop research and marketing strategies for their products. Extension specialists will use the information to identify diseases and disease trends. State and Federal officials responsible for regulatory veterinary medicine will use the information to gain a more complete picture of animal health as a basis for program planning and to direct funding. State and Federal officials will use the data to make scientifically based decisions. Public health officials will use the information to estimate the magnitude of health conditions which affect public health. Research scientists will use the information to define current and future animal health issues and direct research funding. Veterinary and agricultural students will use these data to determine the occurrence, potential risk factors, and cost of animal disease as a foundation for training in health management, animal welfare, nutrition, and environmental impacts. The benefit to the industry from the Dairy 2007 study is scientifically valid national estimates of health and management practices of the nation's dairy industry.

APHIS will use the data collected to:

- Establish national and regional production measures (such as average weaning age) for producer, veterinary, and industry reference.
- Predict or detect national and regional trends in disease emergence and movement.

⁴ A complete list of publications using NAHMS Dairy 2002 data is included in Appendix F.

- Address emerging issues.
- Examine the economic impact of health management practices.
- Provide estimates of both outcome (disease or other parameters such as bulk tank somatic cell count) and exposure (risks and components) variables that can be used in analytic studies in the future by APHIS.
- Provide input into the design of surveillance systems for specific diseases.

Dairy 2007 Study Data Collection Forms

NAHMS-187, <u>General Dairy Management Report</u> – will be administered by a NASS enumerator to collect data on the producer's dairy inventory, management practices, preventive care practices, and chemical applications. A unique NAHMS identification number is assigned to the form. NASS will enter and validate data collected and provide consenting producer questionnaires to the APHIS state NAHMS coordinators, the complete dataset is then sent to NCAHS.

NAHMS-188, <u>Producer Agreement</u> – is presented to the participant by the APHIS-designated data collector upon entry into the NAHMS study. This form is designed to increase the participant's understanding of the study focus, highlight confidentiality safeguards, and explain participation requirements. After completing the form with the participant, it will be signed by the participant and the data collector. One copy of this agreement is left with the participant and one copy is retained by the data collector.

NAHMS-189, <u>VS Initial Visit</u> - will be administered to consenting producers by an APHISdesignated data collector to collect data on management practices. Upon completion, the form (without producer contact information) is returned via U.S. Mail to NCAHS in Fort Collins, Colorado, for data entry and validation. A copy is retained by the data collector to facilitate validation.

NAHMS-190, <u>Heifer Calf Blood Collection Record</u> –will be administered by an APHISdesignated data collector to collect data on productivity over the past year, biosecurity practices, environmental practices, and milking procedures. Upon completion, the form (without producer contact information) is returned via U.S. Mail to the NCAHS for data entry and validation and a copy is retained by the data collector to facilitate validation.

NAHMS-191, <u>Environmental Collection Record</u> – will be used by the Federal veterinary medical officer (VMO) to collect information on the general health of the animals from which blood samples are being collected. The blood samples will be sent to the National Veterinary Services Laboratories for analysis. Test results will be returned to the NCAHS and will be added to the farm record database. The form is returned via U.S. Mail to the NCAHS for data entry and validation and a copy is retained by the data collector to facilitate validation.

NAHMS-192, <u>Bulk Tank Milk and Filter Collection Record</u> – will be used by the Federal VMO to collect information about bulk tank milk samples from dairy operations. Test results will be returned to the NCAHS and will be added to the farm record database. The form is returned via U.S. Mail to the NCAHS for data entry and validation and a copy is retained by the data collector to facilitate validation.

NAHMS-193, <u>Animal Assessments Collection Record</u> – will be used by the Federal VMO to collect information about calf health from each participating farm. Samples will be sent to a state or university laboratory for analysis. Test results will be returned to the NCAHS and will be added to the farm record database. The form is returned via U.S. Mail to the NCAHS for data entry and validation and a copy is retained by the data collector to facilitate validation.

NAHMS-194, <u>VS Second Visit</u> – will be administered to consenting producers by an APHISdesignated data collector to collect data on management practices. Upon completion, the form (without producer contact information) is returned via U.S. Mail to NCAHS in Fort Collins, Colorado, for data entry and validation. A copy is retained by the data collector to facilitate validation.

NAHMS-198, <u>Individual Fecal Collection Record</u> – will be used by the Federal veterinary medical officer (VMO) to collect information on the general health of the animals from which fecal samples are being collected. The fecal samples will be sent to the National Veterinary Services Laboratories for analysis. Test results will be returned to the NCAHS and will be added to the farm record database. The form is returned via U.S. Mail to the NCAHS for data entry and validation and a copy is retained by the data collector to facilitate validation.

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.

No automated, electronic, or mechanical techniques will be used to collect information for the Dairy 2007 study. Since biological samples will be collected, an on-farm visit is required and provides an opportunity for the data collector to administer the questionnaire.

4. Describe efforts to identify duplication.

Literature searches for existing data relevant to the Dairy 2007 study have been performed. Available data were reviewed and compiled from all known sources. Sources reviewed include cooperative state research, private industry and professional publications, diagnostic laboratories, other Federal and State agencies, the National Milk Producers Federation (NMPF), American Association of Bovine Practitioners (AABP) and universities. Personnel from Federal agencies and academia were consulted in their area of expertise to identify areas of potential duplication. No other entity/source is collecting and analyzing this type of information on the health of the U.S. dairy industry.

5. If the collection of information impacts small business or other small entities, describe the methods used to minimize burden.

Producers with fewer than 30 milk cows in inventory during the NASS visit are not eligible for participation in the APHIS data collection phases. This survey is designed to collect the minimum amount of data required from a minimum number of dairy producers to ensure statistically and scientifically valid data. Industry and producer input is solicited to ensure that information collected is relevant and timely. This is a voluntary study; it is at the discretion of the individual dairy producer to decide whether or not it is desirable for them to participate.

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

The status of the U.S. dairy industry has been examined in 1991-92, 1996, 2002, and must continue with the collection of data regarding health and management on dairy operations; such as prevailing production practices and frequency of health problems. In addition, it is imperative that we continue to track disease levels through biologic sample testing, and maintain a bank of sera to preserve the capability to retrospectively examine the U.S. dairy population. The type, quality, and frequency of data collected by the NAHMS through national on-farm collections is unique, no other entity is collecting this type of information in the U.S.

Without this type of national data, the U.S.' ability to detect trends in management, production, and health status, either directly or indirectly, would be reduced or nonexistent. The possibility of assessing the reduction of risk to human health from *E. coli, Salmonella*, or Campylobacter due to management changes based on NAHMS data would also be nonexistent. Furthermore, the ability to respond to international trade issues involving the health status of the U.S. dairy population would be severely reduced, potentially impacting the global marketability of animals, milk, meat and byproducts.

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

This information collection is consistent with guidelines established in 5 CFR 1320.5.

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 recordkeeping, 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.

During 2006, APHIS consulted with the following individuals concerning the Dairy 2007 Study:

Mr. John Adams, Director of Animal Health and Farm Services, National Milk Producers Federation, 2101 Wilson Blvd., Suite 400, Arlington, VA 22201, 703.243.6111

Dr. Todd Byrem, Director, Antel BioSystems, Inc., PO Box 23157, Lansing, MI 48910-3157, 517.351.3180 ext 649

Dr. Ian Gardner, School of Veterinary Medicine, University of California, Davis, Davis, CA 95616, 530.752.6992

The Agency's notice of information collection activity was announced in the Federal Register on Wednesday, November 8, 2006, pages 65453-65454. One comment was received but it did not relate to paperwork.

9. *Explain any decision to provide any payment or gifts to respondents, other than remuneration 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.

APHIS will only release study results based on summary estimates from the inference population. Only the NASS designated agents collecting on-farm data will have knowledge of the participant's identity. All forms, data, and questionnaires will refer to the respondent by a numeric code, which is assigned by NASS. This link between participant and numeric code will be destroyed once data collection, entry, validation, and report dissemination are complete (except in those cases where the producer consented to participation in follow-on studies). All completed survey forms, without names and other identifying personal information, will be stored securely in a limited access records vault. In follow-on phases agreed to by respondents, no names, addresses, or other personal information is recorded on the questionnaire, therefore eliminating any connection between completed questionnaires or laboratory results and the respondent's information.

NASS has statutory protection, under Title 7, Section 2276 of the U.S. Code, Confidentiality of Information, and additionally through the Confidentiality Information Protection and Statistical

Efficiency Act (CIPSEA) of 2002, that guarantees NASS's ability to keep individual farm data and associated producer names and addresses confidential. Acting under the capacity granted to Government statistical agencies, NASS designates APHIS personnel as designated agents providing researchers and field veterinarians with access to record level data critical to project scope.

Every NASS employee and designated agent that may handle a questionnaire, or data coming from a questionnaire, is required to sign a form certifying he/she understands the restrictions on the use of unpublished data. These documents reference protections provided by the aforementioned statutory and regulatory protections. Access to record-level data files is always restricted and these files are only accessible by NASS employees or designated agents. Designated agents are never provided access to NASS respondents' names and addresses without producer consent.

11. Provide additional justification for any questions of a sensitive nature.

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.

A total of 7,762 burden hours are needed to complete the Dairy 2007 study information collection activity. A detailed burden estimate has been included on the enclosed APHIS 71 Form.

Respondent costs: Estimated respondent costs for the information collection proposed is calculated based on an on-farm data collection estimate of \$9.14 per hour⁵. The total respondent cost for the Dairy 2007 Study is \$70,945 (7,762 hours *\$9.14).

13. Provide an estimate of the total annual cost burden to respondents or record keepers resulting from the collection of information (do not include any hour burden shown in items 12 and 14).

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

14. Provide an estimate of annualized cost to the Federal government.

The estimated cost to the Federal Government is \$682,973.64. For more specific information, please see the enclosed APHIS 79 form.

⁵ NASS Farm Labor, published report for 2005, released November 18, 2005, attached in section 6.

15. Explain the reasons for any program changes or adjustments reported in items 13 or 14 of the OMB form 83-I.

This is a reinstatement of 0579-0205 to investigate animal health related issues and examine general health and management practices used on dairy farms.

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 data collection and validation APHIS phase. Data will be entered into a database management system utilizing microcomputers or workstations, and statistical calculations will be performed; e.g., descriptive statistics including frequency distribution, prevalence and point estimates. Variance measures and confidence intervals for the point estimates will be calculated in order to describe the precision of the descriptive statistics generated. Standard errors will be published along with the point estimates. Findings will be utilized as inputs for simulation modeling, so that future events can be modeled.

Considerable effort has been placed on reducing the time between the end of data collection and release of a final publication. Hardcopy information from the study will be made available to dairy producers, universities, researchers, practitioners, animal health related industries, Federal agencies, legislators, and any other interested party. Copies of current and past information from the NAHMS are available at: <u>http://www.aphis.usda.gov/vs/ceah/ncahs/nahms/</u>

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 approval to not display the expiration date for OMB approval on the forms used in this collection.

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

APHIS is able to certify compliance with all provisions under the Act.