FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF COMMUNICATION TESTING FOR VETERINARY PRODUCTS (0910-0689)

TITLE OF INFORMATION COLLECTION: Study on Decisionmaking to Avoid Drug Residues in Dairy Cows

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**

   FDA is authorized by Section 1003(d)(2)(D) of the Federal Food Drug and Cosmetic Act (21 U.S.C. 393) to ensure the safety of foods and veterinary drugs. FDA's Center for Veterinary Medicine (CVM) is responsible for insuring safe levels of drug residues in animals slaughtered for human consumption. Working in partnership with the U.S. Department of Agriculture (USDA) and state agencies, CVM guides, monitors and enforces the compliance of veterinary drug tissue residues. Although dairy cows account for only seven percent of the total number of adult cattle slaughtered for human consumption, they represent approximately 80 percent of adult cattle reported as having violative drug residues. CVM, working with the FDA's Office of Planning's Risk Communications, wants to learn from dairy farmers how to improve CVM's communication strategy to reduce significantly the occurrence of violative drug tissue residues in dairy cows offered for slaughter.

   CVM hopes to understand failures and misunderstandings in safe dairy farming practices that lead to this high rate of violation. With this critical knowledge, CVM will be able to modify messages and campaigns about the safe use of veterinary products in dairy cows, with the objective of reducing violation rates in the meat of slaughtered dairy cows.

2. **Intended use of information:**

   This project will synthesize current expert knowledge and the information collected in this data collection to develop a communications strategy to guide dairy farmers' decision making, along with best practices from industry, academia and government, toward safe practices. The objective is to reduce significantly the occurrence of violative drug tissue residues in dairy cows that are offered for slaughter.

3. **Efforts to identify duplication:**

   No similar data are gathered or maintained by the FDA or are available from other sources known to the FDA.

4. **Consequence to Federal program if the collection is not conducted:**

   Earlier communication campaigns to reduce violative tissues in the human meat supply have failed to understand the problems that dairy farmers face when they must make the decision to slaughter a previously productive dairy cow. If this project is not conducted, FDA expects that CVM communications will continue to face resistance and that violation rates among dairy farmers will remain unacceptably high.

Respondents will be interviewed one time only. There are no legal obstacles to reduce the burden.

5. **Consultations with Persons Outside FDA:**

Experts in dairy cow drug residues at CVM, USDA (Patty Bennett of the USDA Food Safety and Inspection Service), and nine experts outside the Federal Government[1]were consulted for an Expert Panel Workshop facilitated by the contractor on November 30, 2010 in preparation to this data collection. Two representatives from industry were among the participants at that meeting to advise on the extent of the problem of drug residues at slaughterhouses and their methods for dealing with these problems.

6. **Explain any decision to provide payment or gift to respondents:**

Given the length of interview, the circumstances pertinent on most dairy farms in which there is a heavy work burden with limited opportunities for labor replacement, and the sensitivity of the topic (violations result in fines and restrictions), FDA agreed to provide incentives of $50 to those interviewed.

7. **Confidentiality assurances:**

Information provided by respondents will be kept private and anonymous, except as otherwise required by law. This will be communicated to Interviewees by means of scripts read prior to telephone interviews. Interviewees also will be advised of: the nature of the activity; the purpose and use of the data collected; FDA sponsorship; and the fact that participation is voluntary at all times. Because responses are voluntary, Interviewees will be assured that there are no penalties for deciding not to respond, either to the information collection as a whole or to any particular questions.

Only personnel from a contractor conducting the information collection will have access to individual-level interview data. All contracted project staff conducting the information collection must take required measures to ensure the privacy and anonymity of data. Personally identifiable data shall be limited to information that may be required in the process of enrollment. Personally identifiable information will be accessible to only those contractors who need them and will not be linked to interview data. All personally identifiable data will be destroyed following interview data collection. Neither FDA employees nor any employee of any other Agency will have access to this information.

All electronic and hard-copy data will be maintained securely throughout the information collection and data processing phases. While under review, electronic data will be stored in locked files on secured computers; hard-copy data will be maintained in secure building facilities in locked filing cabinets. As a further guarantee of privacy and anonymity, all presentation of data in reports will be in aggregate form, with no links to individuals. Reports will be used only for research purposes and for the development of communication messages. Raw data from data collections that include sensitive information will not be retained once the data have been extracted and aggregated. The

[1] Dr. Richard Erdman of the University of Maryland; Dr. Kate Hussman of the Louisa Farm Veterinary Service; Dr. Gatz Riddell, Executive Vice President of the American Association of Bovine Practitioners; Dr. Craig Shultz, Director of the Pennsylvania Department of Agriculture; Daniel Etzler and Shelley McCurry of Cargill; Bob Cooksey of the Maryland and Virginia Milk Producers Cooperative Association; Doyle Wainbright,, dairy farmer honored for his record of safety, and Laurie Bucher, Chief of the Division of Milk Control at the State of Maryland.

information never becomes part of a system of records containing permanent identifiers that can be used for retrieval.

Communications for testing efforts described in this proposal are typically considered exempt from the "Regulations for the Protection of Human Subjects" in accordance with paragraph (b)(3) of 45 CFR Sec. 46.101. Before data are collected, FDA researchers will obtain an exemption or a full approval for all research from FDA's IRB, the Research Involving Human Subjects Committee.

8. **Questions of a Sensitive Nature**

Near the close of the interview, Interviewees will be asked if they ever had a cow for which a violation was detected. Interviewees will be assured that the information is voluntary and will be treated as private and anonymous, that they don't have to answer, and that the information will not be shared with FDA.

9. **Description of respondents:**

The respondents are dairy producers, selected using the following criteria:

- Approximately half of the interviews will be conducted with individuals representing dairy operations that are known to have violated drug residue regulations within the past five years. The remainder will either be known to not have had a violation in the past five years or whose compliance status is unknown. This two cohort design will enable exploration of potential differences in the mental models of violators and non-violators. FDA will provide the sample list, which will include information about known violation status.

- The sample will comprise dairy operations in four states: California, Wisconsin, Florida, and New York. These states were selected because they have large numbers of dairy farmers and drug residue violations and because they provide good U.S. geographic balance. The goal is to identify equal numbers from each state.

- Interviews will be conducted with individuals who serve as the key decision maker for treatment or culling at the dairy operation, such as dairy herdsman, production manager, or safety manager. For small operations, this may include the dairy owner.

10. **Date(s) to be Conducted:**

August 15, 2011 – September 30, 2011

11. **How the Information is being collected:**

FDA will provide the contractor with the research sample list, including contact information. FDA worked with State government partners to develop the sample list. Researchers will select potential Interviewees from the sample lists and invite them to participate in an interview, following a script (Appendix A). The potential Interviewees will be informed of the length of the interview (average, 45 minutes). Breaks will be allowed for the convenience of the Interviewee. An incentive of $50 will be offered to encourage participation. If the potential Interviewee agrees to participate, the interviewer will schedule a telephone interview at the person's convenience.

Interviewees will be asked their permission to record the conversation to ensure that interview notes are complete. Interviewees will be assured that the Contractor will keep their comments confidential, and also that they will be permitted to not answer any particular question. If an Interviewee does not permit recording, the interviewer will take detailed handwritten notes of the interview. The interviews will be transcribed in the form of short notes, or near-verbatim transcriptions. To preserve confidentiality, names and other potentially identifying information will not be included in the transcripts.

The contractor will conduct 30 interviews by telephone with these dairy decision-makers. The script was developed from information provided by the Expert Panel Workshop that served as Phase I of this project.

Below is a summary of the key topics of the interview:

- Farming operations and Interviewee's role on the farm. Questions in this section will focus generally on the farming operation, including the goals and objectives of the farm and the key challenges currently facing the farming operation. The Interviewee will be asked to describe his or her role and responsibilities on the farm.

- Treating and culling dairy cattle. Questions in this section will probe into the Interviewee's general thoughts on treating dairy cows, including how treatment decisions are made and carried out on the farm. Interviewees will also be asked how decisions regarding culling dairy cattle are made on the farm. Interviewees will be asked to walk through the decision-making process for a typical scenario related to the treatment of mastitis in a cow in later stages of her production cycle.

- Avoiding drug tissue residues. Interviewees will be asked to think about drug tissue residues, including: the importance of avoiding drug tissue residue; the rules and regulations on avoiding drug tissue residues and how those rules and regulations are followed on the Interviewee's dairy farm. Interviewees will be asked to think about the scenario above concerning treating a cow with mastitis and the decisions that might lead to violative drug tissue residue at the time the cow is slaughtered.

- Drug tissue residue violations. Interviewees will be asked to think about how violations may occur and what might happen in the case the violation is detected. At this point, Interviewees will be asked if they have had any violations linked to their farming operation, and if yes, to describe what happened and what they learned from that experience.

- Communications. Interviewees will be asked questions regarding their information seeking on issues related the treatment of their dairy cattle, and their thoughts on how information about avoiding drug residues should best be communicated.

- Closing. Interviewees will be asked to provide a final piece of advice to FDA on helping dairy farmers to avoid violative drug tissue residues in dairy cattle. They will also be asked a few demographic questions.

12. **Description of Statistical Methods**

The method began with the development of an *Expert Model*, which summarizes and integrates the knowledge of experts on a complex topic (in this case, avoiding violative

drug tissue residue in dairy cattle), typically in a graphic form. The Expert Panel Workshop for this project met on November 30, 2011, including both Government employees and nine experts from outside government.

The Expert Model serves as the analytical framework for the design, implementation and structured analyses of in-depth, semi-structured interviews, known as *mental models* interviews, conducted with a sample of individuals representing a stakeholder population of interest (in this case, dairy farmers). The interview is designed to address key topics identified in the Expert Model and allow for other topics to emerge through free expression. Structured qualitative analysis of the interviews against the Expert Model enables identification of the key areas of alignment and critical gaps in the thinking of experts and the stakeholders. The insight generated by such research directly supports the development of targeted outreach and communications strategies.

The transcribed interviews will be coded against the Expert Model. The contractor has a team of experienced coders and analysts who follow a standard set of coding and analysis procedures. Coded interviews will be transferred into a database. Qualitative analyses of the coded segments will assess detailed concepts and their relationships, identify emerging themes and identify any potential differences among the cohorts (violators vs. non-violators). Given the sample size of this qualitative research, statistical analysis will not be performed. The contractor will conduct a qualitative analysis of gaps and alignments of Interviewees' mental models against the Expert Model, for example, by identifying emerging concepts or issues that were not previously identified in the Expert Model. The results of the research, aggregated across each research cohort (violators, non-violators), will be organized into mental model diagrams. The mental models diagram will be constructed in a format that aligns with, and allows for, comparison with the Expert Model.

BURDEN HOUR COMPUTATION:

Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
dairy farmer	30	45	23

REQUESTED APPROVAL DATE: August 1, 2011

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