Pet Event Tracking Network-State, Federal Cooperation to Prevent Spread of Pet Food Related Diseases
0910-NEW
Supporting Statement

A. Justification

1. Circumstances Making the Collection of Information Necessary

Section 1002(b) of the FDA amendments of 2007, mandated that "not later than 1 year after the date of the enactment of this Act, the Secretary shall establish an early warning and surveillance system to identify adulteration of the pet food supply and outbreaks of illness associated with pet food." This legislative action was taken in response to the 2007 outbreak that occurred in companion animals that was associated with the deliberate adulteration of pet food components, such as wheat gluten, with melamine.

In part to fulfill this mandate, the Agency formed the Partnership for Food Protection (PFP) with Federal, State and Local government partners to continue work started at the Gateway to Food Protection 50-State meeting held in August 2008 in St. Louis, Missouri. As part of the PFP, CVM is charged with facilitating the development of the Pet Event Tracking Network (PETNet). CVM assembled a PETNet working group composed of Federal and state government partners. The PETNet working group has determined PETNet will be a secure information exchange network that will allow FDA and the appropriate Federal and State Agencies to share initial reports of food-borne disease outbreaks in pets.

This action also relies on 21 U.S.C. 342 and 342, the adulteration and misbranding sections of the FD&C act respectively.

2. Purpose and Use of the Information Collection

The PETNet program will allow FDA and its State partners to quickly and effectively exchange information about outbreaks of illness in companion animals associated with pet food. FDA has worked closely with its Federal and State partners to develop the PETNet, and believes that it will serve an important function in protecting the public and animal health. PETNet will be a secure, internet-based network comprised of the FDA, other Federal agencies, and State regulatory agencies/officials that have authority over pet food. The Network will provide timely and relevant information about pet food-related incidents to FDA, the States, and other Federal Government agencies charged with protecting animal and public health.

3. Use of Improved Information Technology and Burden Reduction

PETNet is an entirely electronic, internet based system. PETNet members will make reports about pet food related incidents in their jurisdiction and receive reports made by other PETNet members through a secure, internet website (i.e., FoodShield). Use of the system is entirely voluntary. The system will make use of a standardized electronic form housed on FoodShield to collect and distribute basic information about pet food-related incidents. The form contains drop down menu choices. FDA estimates that 100% of the respondents will use electronic means to use this system.

4. Efforts to Avoid Duplication and Use of Similar Information

The information obtained from the participants is not currently available in real time in order to deal with pet food incidents that occur across State lines and which affect large numbers of animals. This system will allow integrated data from multiple sources in a timely and efficient manner which has not been achieved prior to this program.

5. Impact on Small Businesses or Other Small Entities

This is an incident reporting network that does not directly affect small businesses to any degree more than large businesses. An indirect affect of this program would be to contain to a greater extent the occurrence of such outbreaks, which would protect consumers and animals and therefore, create more consumer confidence in the pet food supply.

6. Consequences of Creating the Information Less Frequently

The information cannot be collected less frequently because it is collected as an outbreak occurs. There is ongoing data collection. To collect this information less frequently would reduce the effectiveness and usability of the data sources.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

In order to be useful the information must be collected as incidents occur and on an ongoing basis. This would foster interstate and Federal-State cooperation.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the Federal Register on July 27, 2010 (75FR43990). FDA received 12 comments on the 60 day notice, 11 from private citizens and one from a veterinary association. None of the comments addressed paperwork issues. Ten of the comments generally supported the PETNet concept, while two comments generally did not support it.

Several comments suggested that it be mandatory, rather than voluntary, for all 50 States to participate in PETNet. FDA declines to follow the comments' suggestion, but

we note that invitations have been sent to all 50 States requesting their participation in PETNet, and at this time 35 States have responded that they will participate in the program.

Several comments stated that the information in PETNet should be publicly available and not just available to Federal and State pet food regulators. FDA disagrees with this comment. Much of the information shared through PETNet will be preliminary reports of potential pet food problems that turn out to be false or to otherwise have no public health significance. FDA and State agencies routinely receive these types of reports and follow up on them without notifying the public. FDA believes that State and Federal regulators can decide how to best use the information in PETNet, including how to use their resources to determine if a pet food incident warranting public notification exists.

One comment recommended that FDA "closely assess reported incidents as soon as possible to ensure no confounding factors bias any determination of a need for a pet food recall." To assist in this effort, the comment recommended that FDA incorporate drop down menus in the PETNet reporting form to collect information about whether the adverse event was confirmed (versus suspected) to have been caused by pet food, if the exposure was acute or chronic, and the clinical outcome of the case.

PETNet will be an additional information resource used by FDA, but will not change FDA's current process for determining the need for pet food recalls. The information AVMA recommends FDA collect will be considered by pet food regulatory professional in deciding whether to enter a report into PETNet. Some of the recommended information may also be derived from the current PETNet form. For example, question # 11 asks if the reporter has laboratory results available to share. Laboratory results are key factors in confirming whether an adverse event is caused by a pet food. Answers to question #8 will provide an indication about duration of exposure, and some clinical outcomes can be derived form question # 6.

One comment stated that the focus of PETNet is wrong and that United States Department of Agriculture (USDA) should be involved because it is their responsibility to inspect pet food plants. FDA notes that it is FDA, not USDA that is responsible for ensuring the safety of pet food, and that FDA conducts inspections of pet food manufacturing establishments. However, USDA is a Federal agency that can contribute to PETNet and USDA has been invited/will participate in PETNet. Another comment stated that PETNet "lacks data security" and is a "needlessly invasive project" whose object to "identify tainted doggie food" is of questionable value. With respect to data security, the data shared through PETNet is contained on a database limited to State and Federal government officials, and the data collection form has been designed such that it is highly unlikely to contain confidential or trade secret information that requires additional data protection measures. Additionally, the agency disagrees that the project is invasive since it is just a method of sharing existing information among State and Federal regulators. Finally, the objective of the project is to protect animal health is valid and consistent with FDA's mission.

9. Explanation of any Payment or Gift to Respondents

There were no gifts or payments to respondents.

10. Assurance of Confidentiality Provided to Respondents

PETNet is comprised of Federal and State regulatory officials (respondents) who will report information about pet food related incidents in their jurisdiction by answering questions on a standardized electronic form. The form is housed on a secure internet site that is not available to the public, and only PETNet members and not the public will be able to make or receive reports. The standardized form has been designed as questions with drop down answers, and will not contain any personal information such as the names or addresses of veterinarians, pet owners, or others involved in a pet food incident. The PETNet form will, however, ask for the name and contact information for the reporter (i.e., the Federal or State regulatory official making the report in PETNet) so that other PETNet members can follow-up with the reporter for further information or questions about the reported incident.

11. Justification of Sensitive Questions

FDA is not asking questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

Table 1. Estimated Reporting Burden

21 U.S.C. 342 & 343/Section 1002(b) 2007 FDA Amendments	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Form 3756	50	10	500	20/60	167

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

FDA estimates that each State will report (e.g. fill out the PETNet form to alert other PETNet members about a pet food-related incident) approximately 10 times per year. FDA estimates that 20 minutes is sufficient time to fill out the form. State regulatory officials responsible for pet food already possess computer systems and have the internet access necessary to participate in PETNet, and thus there are no capital expenditures associated with the reporting.

Regarding recordkeeping, State regulatory officials who report on PETNet receive the reportable information from consumers in the course of their customary and regular duties. Further, these individuals already maintain records of such consumer complaints in the course of their duties which are sufficient for the purposes of reporting on PETNet. Therefore, FDA believes that the proposed collection of information does not have additional recordkeeping requirements.

12b. Annualized Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Veterinarian and Other Scientific and Technical State Specialists[1]	167	$43.50	$7264.50

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no other costs.

14. Annualized Cost to the Federal Government.

We estimate that 1 FTE for a GS-14 Consumer Safety Officer will be required ($105,211 annually).

15. Explanation for Program Changes or Adjustments

New program.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no such plans.

17. Reasons Display of OMB Expiration Date is Inappropriate

Display is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

[1] May 2009--Bureau of Labor Statistics, Occupational Employment and Wage Estimates for State Government. Veterinarians and Other Professional Scientific and Technical Services.