Tracking Network for PETNet, LivestockNet, and SampleNet

OMB Control No. 0910-0680

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Center for Veterinary Medicine and the Partnership for Food Protection developed a web-based Tracking Network for PETNet, LivestockNet, and SampleNet (the tracking network) to allow Federal, State, and Territorial regulatory and public health agencies to share safety information about animal food. Information is submitted to the tracking network by regulatory and public health agency employees with membership rights. The efficient exchange of safety information is necessary because it improves early identification and evaluation of a risk associated with an animal food product. We use the information to assist regulatory agencies to quickly identify and evaluate a risk and take whatever action is necessary to mitigate or eliminate exposure to the risk. Earlier identification and communication with respect to emerging safety information may also mitigate the potential adverse economic impact for the impacted parties associated with such safety issues. The tracking network was developed under the requirements set forth under section 1002(b) of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Pub. L. 110-085). Section 1002(b) of FDAAA required FDA, in relevant part, to establish a pet food early warning alert system.

The tracking network collects: (1) reports of pet food related illness and product defects associated with dog food, cat food, and food for other pets, which are submitted via the Pet Event Tracking Network (PETNet); (2) reports of animal food-related illness and product defects associated with animal food for livestock animals, aquaculture species, and horses (LivestockNet); and (3) reports about animal food laboratory samples considered adulterated by State or FDA regulators (SampleNet).

PETNet, LivestockNet, and SampleNet reports collect similar information: product details about the subject of the report; the risk of illness or defect associated with the product; the animal(s) affected; and identifying information about the submitter. The SampleNet report instrument recently was approved as a nonsubstantive change to a currently approved collection. This request seeks extension of OMB approval of the tracking network as well as approval of the 100 additional expected responses and 25 hours that will occur once the SampleNet portion of the tracking network is made available to submitters.

2. Purpose and Use of the Information Collection

As noted, information is submitted to the Tracking Network for PETNet, LivestockNet, and SampleNet by regulatory and public health agency employees with membership rights. The efficient exchange of safety information is necessary because it improves early identification and evaluation of a risk associated with an animal food product. We use the information to assist regulatory agencies to quickly identify and evaluate a risk and take whatever action is necessary to mitigate or eliminate exposure to the risk.

3. Use of Improved Information Technology and Burden Reduction

The Tracking Network for PETNet, LivestockNet, and SampleNet is an entirely electronic, internet-based system. Its members make reports about animal food-related incidents in their jurisdiction and receive reports made by other members through a secure, internet website (www.animalfeednetwork.net). FDA estimates that 100% of the respondents will use electronic means to use this system.

4. Efforts to Identify Duplication and Use of Similar Information

There is no duplication of reporting requirements. FDA and the U.S. Department of Agriculture (USDA) agencies, the Animal and Plant Health Inspection Service (APHIS) and the Food Safety and Inspection Service (FSIS), have different regulatory responsibilities with respect to animal feed and ensuring food safety.

5. Impact on Small Businesses or Other Small Entities

None of the respondents are small businesses; they are Federal, State, and Territorial regulatory and public health agency employees.

6. Consequences of Collecting the Information Less Frequently

Data collection occurs occasionally. The data is collected as an outbreak occurs. The information cannot be collected less frequently because doing so would reduce the effectiveness and usability of the data collected.

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

There are no special circumstances associated with this collection of information.

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 March 15, 2016 (81 FR 13794). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

FDA does not provide any payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

The tracking network does not contain an assurance of confidentiality. However, all information received by FDA is subject to the agency's regulations concerning confidentiality in 21 CFR 20.61. Confidential commercial information is protected from disclosure under the Freedom of Information Act under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)), and by part 20 of the agency's regulations (21 CFR part 20).

11. Justification for Sensitive Questions

This information collection does not involve questions that are of a personally sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

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

Table 1.—Estimated Annual Reporting Burden

Activity	Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
PETNet	20	5	100	0.25 (15 minutes)	25
LivestockNet	20	5	100	0.25 (15 minutes)	25
SampleNet	20	5	100	0.25 (15 minutes)	25
Total					75

Our estimate is based on our experience with the tracking network over the past 3 years. We estimate that we will receive an average of 5 submissions from 20 respondents for each type of report, and that it will take 15 minutes (0.25 hour) per response.

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	75	$47.59	$3569.25

May 2015--Bureau of Labor Statistics, Occupational Employment and Wage Estimates for State Government. Veterinarians and Other Professional Scientific and Technical Services.

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

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

There are no annualized costs to the Federal Government.

15. Explanation for Program Changes or Adjustments

The reporting burden has been adjusted to reflect an increase in additional SampleNet reports. We estimate an increase in the number of responses by 100, and an increase in the total hour burden by 25 hours.

16. Plans for Tabulation and Publication and Project Time Schedule

There is no intent on the part of the Federal Government to publish this data, nor is any general statistical analysis by the Federal Government anticipated.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

We are not seeking approval to not display the OMB expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.