UNITED STATES FOOD & DRUG ADMINISTRATION

Tracking Network for PETNet, LivestockNet, and SampleNet

OMB Control No. 0910-0680

SUPPORTING STATEMENT

**Part A – Justification**:

1. Circumstances Making the Collection of Information Necessary

The Food and Drug Administration's (FDA, the agency, us or we) Center for Veterinary Medicine (CVM) 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).

We are therefore requesting extension of OMB approval for information collection associated with the CVM tracking network discussed in this supporting statement.

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

We are unaware of duplicative information collection.

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

We published a 60-day notice inviting public comment on the proposed collection of information in the *Federal Register* of November 22, 2019 (84 FR 64533). We received one comment offering general support for the information collection, but the comment did not suggest we change our burden estimate. Upon our own reevaluation of the collection, however we noted a significant decrease in the number of respondents from that included in our 60-day notice. We revised our estimate and again invited public comment in the *Federal Register* of March 30, 2020 (85 FR 17583); no comments were received.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

In preparing this Supporting Statement we consulted with our Privacy Office to ensure appropriate handling of the information collected. FDA determined that although personally identifiable information (PII) is collected, FDA does not use PII to routinely retrieve records from the information collection. The PII collected is needed to gain access to the network which collects reports of pet food related illness and product defects associated with dog food, cat food, and food

for other pets (PETNet); reports of animal food-related illness and product defects associated with animal food for livestock animals, aquaculture species, and horses (LivestockNet); and reports about animal food laboratory samples considered adulterated by State or FDA regulators (SampleNet). 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

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

*12a. Annualized Hour Burden Estimate*:

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 | 5 | 5 | 25 | 0.25 (15 mins.) | 6.25 |
| LivestockNet | 5 | 5 | 25 | 0.25 (15 mins.) | 6.25 |
| SampleNet | 5 | 5 | 25 | 0.25 (15 mins.) | 6.25 |
| TOTAL | | | | | 18.75 |

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 5 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[1] | 18.75 | $56.00 | $1,050 |

[1] May 2018--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/Recordkeepers or Capital Costs

There are 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 information collection reflects adjustment. By reducing the number of respondents, the overall burden reflects a decrease of 225 responses and 56.25 hours annually. This is consistent with our evaluation of the information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

This information collected will not be published or tabulated.

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.