DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0368]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Pet Event Tracking Network—State, Federal Cooperation To Prevent Spread of Pet Food Related Diseases

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by January 24, 2011.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910-new and title Pet Event Tracking Network—State, Federal Cooperation to Prevent Spread of Pet Food Related Diseases. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Johnny Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7651, *Juanmanuel.vilela@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Pet Event Tracking Network (PETNet)—State, Federal Cooperation To Prevent Spread of Pet Food Related Diseases—(OMB Control Number 0910-New)

In August 2008, FDA sponsored the "Gateway to Food Protection" meeting, also known as the "50–State" meeting. The meeting included representatives from other Federal Agencies, the States, localities, territories, and tribal partners, and was held to address the challenges necessary to ensure the safety of the U.S. food supply. Work groups were formed during the meeting which met and produced recommendations in specific topic areas. One of the workgroups, the Outbreaks/Food-Borne and Feed-Borne Investigations Workgroup, created a subgroup consisting of veterinarians, animal feed regulators, and others involved with animal health issues. This subgroup developed an ambitious proposal for an early warning system to identify, track, and report disease outbreaks in companion animals or contamination incidents concerning pet food or animals feed, which they named "The Pet Event Tracking Network" (PETNet). The PETNet proposal was developed 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. As envisioned by the subgroup at that time, PETNet would include a system for reporting outbreaks and would be supported by adequate diagnostic laboratory facilities and an established mechanism for conducting national epidemiological investigations.

The PETNet subgroup subsequently met twice in face-to-face meetings, in May and November 2009, during which time the proposed scope of PETNet was streamlined to focus the program on information sharing, rather than epidemiology or other aspects. One of the main concerns of FDA's State regulatory partners regarding FDA's handling of the melamine incident was that many States provided information to FDA, but the information reported by the States to FDA and other information in the possession of FDA was not shared by FDA with the States. States believed that if they had received more information about what was going on in a timely manner, they could perhaps have taken appropriate action to safeguard animal and the public health by using their own regulatory authorities and resources. The Agency agreed with the States, and thus decided to focus PETNet on being a system for sharing information between FDA, other Federal Agencies, and the States about food-borne illness outbreaks in companion animals. By the end of the November 2009, meeting, this revised vision of PETNet was firmly established with many of the details about the system in place.

FDA is planning to implement an initiative called PETNet that 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 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. FDA intends to identify and invite State participants from all 50 States to participate in PETNet. Members of the network will be able to both receive alerts about pet food incidents, as well as create alerts when they are aware of a pet food incident within their jurisdiction. The information will be used to help State and Federal regulators determine how best to use inspectional and other resources to either prevent or quickly limit the adverse events caused by adulterated pet food. Many States have regulatory authority beyond that of FDA and often can be in a position to act independently of FDA with the information they will receive from the PetNet.

Use of the system, including the reporting of incidents by States to FDA, will be entirely voluntary. The PETNet system will be housed in Food Shield, a proprietary software system, and will be accessible only to members via password. 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 the following data elements, almost all of which are drop down menu choices: The species involved, clinical signs, number of animals exposed, number of animals affected, animal ages, date of onset, name and type of pet food involved, the manufacturer and distributor of the pet food (if known), the State where the incident occurred, the origin of the information, whether there are supporting laboratory results, and contact information for the reporting PETNet member (*i.e.*, name, telephone number). The form would be filled out and submitted by a PETNet member on FoodShield, at which time it will be available to other PETNet members. Thus, the information will be entered and received by PETNet members in as close to real time as possible. FDA has designed the form itself to contain only the essential information necessary to alert PETNet members about pet food-related incidents. For further information, such as laboratory results, PETNet members

can contact the reporting PETNet member.

In the **Federal Register** of July 27, 2010 (75 FR 43990), FDA published a 60-day notice requesting public comment on the proposed collection of information. 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 followup 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 the American Veterinary Medical Association 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 the U.S. 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.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 U.S.C. 342 & 343/Section 1002(b) of the 2007 FDA amendments act/form FDA	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Form FDA 3756	50	10	500	20/60	167

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA estimates that each State will report (*i.e.,* fill out the PETNet form to alert other PETNet members about a pet food-related incident) approximately 10 times per year. This estimate represents the maximum number of reports that FDA expects a State to submit in a year, and in many cases the number of reports submitted by a State will probably be far less. FDA believes that, given the form only has 11 items and most are drop down fields, 20 minutes is a sufficient amount of time to complete 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 their States 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.

Dated: December 16, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–32275 Filed 12–22–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0466]

Compliance Policy Guide Sec. 527.300 Dairy Products—Microbial Contaminants and Alkaline Phosphatase Activity; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of Compliance Policy Guide Sec. 527.300 Dairy Products—Microbial Contaminants and Alkaline Phosphatase