associated with drug response, CVM would potentially have a scientific basis for modifying recommendations with regard to SLENTROL use.

To conduct the study, FDA would seek the voluntary participation of veterinarians in the private sector. FDA would contact veterinarians who have reported adverse events with SLENTROL to FDA using a Form FDA 1932a, or veterinarians who have posted adverse experiences with SLENTROL on Internet Web sites or other public forums with their contact information, to ask them if they are willing to participate in the study. If the veterinarians are willing to participate, and the owners of the animals consent, FDA would provide the veterinarians with a package that includes instructions and materials for taking a blood sample and buccal swab from the animal, a postage paid envelope to return the samples, and a brief "Sample Collection" form to be filled out by the veterinarian. The "Sample Collection" form collects information that includes the date and type of sample taken, information about the treated dog (breed, age, gender and neuter status, type of food), and information about past SLENTROL use and adverse events experienced. FDA anticipates that participating veterinarians will take the samples during routine office visits from pet owners for their pets, and that pet owners will not make a special trip to the veterinarian for the purpose of participation in the study. FDA's goal is to obtain at about 100 samples.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 U.S.C. 512/ Form FDA	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
3754	100	1	100	0.5	50

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 U.S.C. 512/ Form No.	No. of Record-keepers	Annual Frequency per per Record-keeping	Total Annual Records	Hours per Record	Total Hours
3754	100	1	100	0.5	50

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

FDA's estimates that it will take a veterinarian approximately 30 minutes to obtain the owner's consent, take the blood and buccal samples, and fill out the "Sample Collection" form. This includes the time necessary for a veterinarian to read instructions for taking samples, to search the animal's medical records to obtain information necessary to complete the form, such as the adverse events that occurred after initiating SLENTROL treatment, and to mail the samples and form to FDA. As noted previously, FDA anticipates that participating veterinarians will obtain the samples during routine office visits from the pet owner for their pet, and therefore no reporting burden is contained in this collection of information with respect to the owners of the animals involved in the study.

Regarding recordkeeping, it is the customary and usual practice of veterinarians to keep medical records for their patients, and the agency believes that the proposed collection of information would not contain any additional recordkeeping burdens. However, FDA has estimated that an additional 30 minutes of recordkeeping will be necessary to maintain records necessary to participate in the study.

Dated: July 21, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–18304 Filed 7–26–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2010–N–0368]

Agency Information Collection Activities; Proposed Collection; 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 an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on the paperwork requirements for the proposed Pet Event Tracking Network (PETNet) cooperative Federal and State initiative.

DATES: Submit either electronic or written comments on the collection of information by September 27, 2010.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793, *Denver.presley@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section

3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Pet Event Tracking Network—State, Federal Cooperation to Prevent Spread of Pet Food Related Diseases—21 U.S.C. 342 and 343, Section 1002(b) of the FDA Amendments Act of 2007. Stat. 823 (2007) (OMB Control No. 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 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 "The Pet Event Tracking Network" (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 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. 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 the FDA and often can be in a position to act independently of FDA with the information they will receive from the Pet Event Tracking Network.

Use of the system, including the reporting of incidents by States to the 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.

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

TABLE 1.—ESTIMATED REPORTING BURDEN

21 U.S.C. Section 342 & 343/Section 1002(b) 2007 Amendments / Form FDA	No. 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: July 21, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–18303 Filed 7–26–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of Federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Therapeutics for the Treatment and Prevention of Atherosclerosis and Cardiovascular Disease

Description of Invention: This technology consists of peptides and peptide-analogues that enhance clearance of excess cholesterol in cells and do not exhibit the cytotoxicity that has hampered development of similar potential therapeutics.

Briefly, apolipoprotein A–1 (ApoA–1) promotes cholesterol efflux from cells and its concentration is inversely correlated with atherosclerotic events. The isolated peptidic component of ApoA–1 that acts within the cholesterol secretion pathway is therapeutic towards atherosclerosis but exhibits cytotoxic effects. In contrast, our inventors have derivatized that ApoA–1 peptide which is both less cytotoxic and more active than the underivatized component in initial studies. This potential therapeutic is similar to high density lipoprotein (HDL) therapy and may complement statin-mediated reduction of pro-atherogenic lipoproteins.

Potential Applications

- Treatment and prevention of atherosclerosis.
- Treatment and prevention of cardiovascular disease, coronary artery disease, heart attack, stroke and inflammation.
- Therapeutic or preventative coating for a heart or vascular implant.
- Alternative to HDL therapy.

Potential Advantages

- Enhanced cytotoxicity profile.
- Enhanced hydrophilicity profile.
- Complements statin-based therapies.
- Oral delivery approaches in development.

Development Status: Early stage with in vitro proof of concept data.

Market: The CDC indicates that heart attacks account for 26% of deaths in the United States of which atherosclerosis is a significant contributing factor or cause. Global sales for cardiovascular therapeutics are expected to exceed $50b in 2010.

Inventors: Amar A. Sethi (NHLBI) *et al.*

Patent Status: U.S. Provisional Application No. 61/265,291 filed 30 Nov 2009 (HHS Reference No. E–047–2009/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Fatima Sayyid. M.H.P.M.; 301–435–4521; *Fatima.Sayyid@nih.hhs.gov.*

Use of Immunosuppressive Agents for Treatment of Age-related Macular Degeneration (AMD) and Diabetic Retinopathy

Description of Invention: AMD belongs to a group of disorders in which the immune system may play an important role. This invention discloses that patients with AMD gain additional therapeutic benefit from combination treatment of immunosuppressive agents and standard-of-care in comparison to standard-of-care alone. This invention slows the progression of choroidal neovascularization (CNV) and may have implications for related pathologies, including diabetic retinopathy. Clinical data from a small, randomized pilot clinical trial are available.

Applications

- A method of treatment for AMD.
- A method of treatment for diabetic retinopathy.
- A method of treatment for diseases associated with CNV.

Advantages

- Likely to be synergistic with existing therapeutics.
- May enable repurposing of some exiting immunosuppressive agents.