ANNUAL BURDEN ESTIMATES

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Average burden hours per response</th>
<th>Total burden hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>RFP and Contract</td>
<td>50</td>
<td>1.54</td>
<td>1.50</td>
<td>115.50</td>
</tr>
<tr>
<td>Emergency Funding Request</td>
<td>27</td>
<td>1</td>
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<td>Service Agreements</td>
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<td>1</td>
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<td>14</td>
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<tr>
<td>Biennial Reports</td>
<td>50</td>
<td>1</td>
<td>1.50</td>
<td>75</td>
</tr>
<tr>
<td>Advance Planning Document</td>
<td>50</td>
<td>1.84</td>
<td>60</td>
<td>5,520</td>
</tr>
<tr>
<td>Estimated Total Annual Burden Hours:</td>
<td></td>
<td></td>
<td></td>
<td>5,751.50</td>
</tr>
</tbody>
</table>

**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 sample collection plan for dogs treated with the drug SLENTROL.

**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 Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–396–3793.

**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.

**Sample Collection Plan for Dogs Treated With SLENTROL—21 CFR 514.80 (OMB Control Number 0910–NEW)**

FDA’s Center for Veterinary Medicine (CVM) is planning a pharmacogenomic study to examine whether adverse drug events (ADEs) experienced with SLENTROL, an anti-obesity drug approved for dogs, are associated with genetic variations in the dogs treated. Pharmacogenomics involves the use of genome-wide analyses to identify genes with altered expression or activation as a result exposure to a drug. Preliminary analysis by CVM has indicated potential correlations between dog breeds and some ADEs. The study would collect a blood sample and buccal swab from animals that have been treated with SLENTROL and experienced specific ADEs (i.e., reactors), and animals that have been treated with SLENTROL and that have not experienced ADEs (i.e., controls). The samples would be analyzed by FDA using microarray analysis and single nucleotide polymorphism analysis to determine possible genetic variations associated with the ADEs reported. If this project identifies definite genotype mutations...
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>
<thead>
<tr>
<th>TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>21 U.S.C. 512/ Form FDA</td>
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<tr>
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<td>3754</td>
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</table>

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

<table>
<thead>
<tr>
<th>TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹</th>
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<td>21 U.S.C. 512/ Form No.</td>
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<td>3754</td>
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</tbody>
</table>

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


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.

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