DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0308]

Agency Information Collection Request; 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

In compliance with the requirements of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed information collection request for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency’s functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden. To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, e-mail your request, including your address, phone number, OMB number, and OS document identifier, to Sherette.Funncoleman@hhs.gov, or call the Reports Clearance Office on (202) 690–6162. Written comments and recommendations for the proposed information collections must be directed to the OS Paperwork Clearance Officer at the above e-mail address within 60 days.

Proposed Project: The Effect of Reducing Falls on Acute and Long-Term Care Expenses OMB No. 0990–0308—Extension—Assistant Secretary Planning Evaluation (ASPE).

Abstract: ASPE is conducting a demonstration and evaluation of a multi-factorial fall prevention program to measure its impact on health outcomes for the elderly as well as acute and long-term care use and cost. The study is being conducted among a sample of individuals with private long-term care insurance who are age 75 and over using a multi-tiered random experimental research design to evaluate the effectiveness of the proposed fall prevention intervention program. The project will provide information to advance Departmental goals of reducing injury and improving the use of preventive services to positively impact Medicare use and spending. The project began in Spring 2008 and is expected to be completed in Spring 2013.

ESTIMATED ANNUALIZED BURDEN TABLE

<table>
<thead>
<tr>
<th>Forms (if necessary)</th>
<th>Type of respondent</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>Initial Telephone Screen</td>
<td>Active Control Group (ACG)/Experimental Group (EG)</td>
<td>2400</td>
<td>1</td>
<td>20 minutes</td>
<td>800 hours</td>
</tr>
<tr>
<td>In-person interview</td>
<td>EG</td>
<td>1200</td>
<td>1</td>
<td>1.25 hours</td>
<td>1,500 hours</td>
</tr>
<tr>
<td>Jump start phone call</td>
<td>EG</td>
<td>1200</td>
<td>1</td>
<td>30 minutes</td>
<td>600 hours</td>
</tr>
<tr>
<td>Quarterly phone calls</td>
<td>ACG/EG</td>
<td>10 minutes</td>
<td>1</td>
<td>10 minutes</td>
<td>1,220 hours</td>
</tr>
<tr>
<td>Final Telephone Screen</td>
<td>ACG/EG</td>
<td>1766</td>
<td>1</td>
<td>20 minutes</td>
<td>589 hours</td>
</tr>
<tr>
<td>Final in-person interview</td>
<td>EG</td>
<td>884</td>
<td>1</td>
<td>1.25 hours</td>
<td>1,105 hours</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>5,814 hours</strong></td>
</tr>
</tbody>
</table>

Seleda Perryman,
Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.

[FR Doc. 2010–2496 Filed 2–4–10; 8:45 am]
BILLING CODE 6820–14–P
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on How to Submit a Notice of Intent to Slaughter for Human Food Purposes in Electronic Format to the Center for Veterinary Medicine

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, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the reporting requirements for the information collection on how to submit a notice of intent to slaughter for human food purposes in electronic format to the Center for Veterinary Medicine (CVM).

DATES: Submit written or electronic comments on the collection of information by April 6, 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, 301–796–3793.

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 the agency. 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, including each proposed extension of an existing 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.

Guidance for Industry on How to Submit a Notice of Intent to Slaughter for Human Food Purposes in Electronic Format to the Center for Veterinary Medicine—Section 512(j) of the Federal Food, Drug, and Cosmetic Act (OMB Control Number 0910–0450)—Extension

Section 512(j) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(j)) gives FDA the authority to set conditions under which animals treated with investigational new animal drugs may be marketed for food use. Under this authority, CVM issues to a new animal drug sponsor (sponsors) a slaughter authorization letter that sets the terms under which investigational animals may be slaughtered. The U.S. Department of Agriculture (USDA), also monitors the slaughter of animals treated with investigational new animal drugs under the authority of the Meat Inspection Act (21 U.S.C. 601–695).

Sponsors must submit slaughter notices each time investigational animals are presented for slaughter, unless this requirement is waived by an authorization letter (21 CFR 511.1(b)(5) and 9 CFR 309.17). These notifications assist CVM and USDA in monitoring the safety of the food supply. Slaughter notices were previously submitted to CVM and USDA in paper format. CVM’s guidance on “How to Submit a Notice of Intent to Slaughter for Human Food Purposes in Electronic Format to the Center for Veterinary Medicine” provides sponsors with the option for submitting a slaughter notice as an e-mail attachment to CVM and USDA by the Internet. The electronic submission of slaughter notices is part of CVM’s ongoing initiative to provide a method for paperless submissions. The likely respondents are new animal drug sponsors.

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

<table>
<thead>
<tr>
<th>Section of the act/FDA Form #</th>
<th>No. of Respondents</th>
<th>Annual Frequency per Response</th>
<th>Total Annual Responses</th>
<th>Hours per Responses</th>
<th>Total Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>512(j)/3488</td>
<td>40</td>
<td>0.4</td>
<td>164</td>
<td>.08</td>
<td>1.3</td>
</tr>
</tbody>
</table>

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

2 Electronic submissions received between January 1, 2008, and December 31, 2008.

The number of respondents in table 1 of this document is the number of sponsors registered to make electronic submissions (40). The number of total annual responses are based on a review of the actual number of submissions made between January 1, 2008, and December 31, 2008. Sixteen total annual responses times .08 hours per response = 1.3 total hours.

Submitting a slaughter notice electronically represents an alternative...