Guidance for Industry on How to Submit Information in Electronic Format to the Center for Veterinary Medicine Using the FDA Electronic Submission Gateway—21 CFR 11.2 (OMB Control Number 0910–0454)—Extension

CVM accepts certain types of submissions electronically with no requirement for a paper copy. These types of documents are listed in public docket 97S–0251 as required by 21 CFR 11.2. CVM’s ability to receive and process information submitted electronically is limited by its current information technology capabilities and the requirements of the Electronic Records; Electronic Signatures final regulation. CVM’s guidance entitled “Guidance for Industry: How to Submit Information in Electronic Format to CVM Using the FDA Electronic Submission Gateway” outlines general standards to be used for the submission of any information by e-mail.

The likely respondents are sponsors for new animal drug applications.

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

<table>
<thead>
<tr>
<th>21 CFR Section/FDA Form 3538</th>
<th>No. of Respondents</th>
<th>Annual Frequency per Response</th>
<th>Total Annual Responses</th>
<th>Hours per Response</th>
<th>Total Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>11.2</td>
<td>40</td>
<td>1.3</td>
<td>52</td>
<td>.08</td>
<td>4.2</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 July 1, 2005, and June 30, 2006.

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 is based on a review of the actual number of such submissions made between January 1, 2008 and December 31, 2008, (52 x hours per response (.08) =4.2 total hours).


David Dorsey,
Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2010–2523 Filed 2–4–10; 8:45 am]
BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

National Center for Complementary & Alternative Medicine; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Complementary and Alternative Medicine Special Emphasis Panel Training.

Date: March 1, 2010.
Time: 8 a.m. to 5 p.m.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Biomedical Imaging and Bioengineering Special; 2010/05 SBIR Review.

Date: February 24, 2010.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict: Neurodevices, Bioengineering and Biomodeling.

Date: February 24, 2010.