TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN

<table>
<thead>
<tr>
<th>Activity/21 CFR Section</th>
<th>Number of recordkeepers</th>
<th>Number of records per recordkeeper</th>
<th>Total annual records</th>
<th>Average burden per recordkeeping</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Original—812.140</td>
<td>356</td>
<td>1</td>
<td>356</td>
<td></td>
<td>10</td>
</tr>
<tr>
<td>Supplemental—812.140</td>
<td>356</td>
<td>12</td>
<td>4,272</td>
<td></td>
<td>58</td>
</tr>
<tr>
<td>Nonsignificant—812.140</td>
<td>356</td>
<td>1</td>
<td>356</td>
<td></td>
<td>6</td>
</tr>
<tr>
<td>Total</td>
<td>1,068</td>
<td></td>
<td>8,050</td>
<td></td>
<td>9,968</td>
</tr>
</tbody>
</table>

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

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN

<table>
<thead>
<tr>
<th>Activity/21 CFR Section</th>
<th>Number of respondents</th>
<th>Number of disclosures per respondent</th>
<th>Total annual disclosures</th>
<th>Average burden per disclosure</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reports for Nonsignificant Risk Studies—812.150</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>6</td>
<td>6</td>
</tr>
</tbody>
</table>

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

For Further Information Contact:
Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–410B, Rockville, MD 20850, JonnaLynn.capezzuto@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.

Antiparasitic Drug and Resistance Survey—21 CFR Part 514.4 (OMB Control Number 0910–NEW)

Resistance of parasites to one or more of the major classes of FDA approved antiparasitic drugs is a documented problem in cattle, horses, sheep, and goats in the United States. The results from this survey will provide FDA information that can be used to make decisions about future approaches to antiparasitic drugs. FDA will make the results of the survey publicly available.

FDA plans to survey members of veterinary professional organizations using an Internet-based survey instrument. The questions in the survey are designed to elicit professional opinions regarding the use of antiparasitic drugs and the awareness of antiparasitic drug resistance. The survey will query subjects on topics including: (1) Awareness of the issues related to antiparasitic resistance, (2) methods currently being used to detect and/or monitor for antiparasitic resistance, (3) management practices being used or recommended to manage or reduce antiparasitic resistance, and (4) labeling and marketing considerations for antiparasitic drugs.

FDA published a 60-day notice in the Federal Register on July 13, 2010 (75 FR 38088). Following public comment on the proposed survey, and published a 30-day notice on May 23, 2011 (76 FR 28138).
FDA will conduct a pre-test of the survey with five respondents, and it is estimated that it will take 30 minutes (0.5 hour) to complete the pretest, for a total of 2.5 hours. We estimate that 650 respondents will complete the survey. It is estimated that it will take a respondent 30 minutes (0.5 hour) for a total of 325 hours. Thus, the total estimated annual reporting burden is 327.5 hours. FDA’s burden estimate is based on prior experience with consumer surveys that are similar.


Leslie Kux, Assistant Commissioner for Policy.

[FR Doc. 2012–29094 Filed 11–30–12; 8:45 am]

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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; Topics in Nanotechnology and Tissue Engineering.

Date: December 5, 2012.

Time: 8:30 a.m. to 5:00 p.m.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; 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; Topics in Nanotechnology and Tissue Engineering.

Date: December 5, 2012.

Time: 11:00 a.m. to 3:00 p.m.