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.

**TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN**

<table>
<thead>
<tr>
<th>21 CFR Section/activity</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>501.22(k); labeling of color additive or lake of color additive; labeling of color additives not subject to certification.</td>
<td>3,120</td>
<td>0.8292</td>
<td>2,587</td>
<td>0.25 (15 minutes)</td>
<td>647</td>
</tr>
</tbody>
</table>

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

Having become effective November 18, 2013, we estimate that the burden associated with the labeling requirements under § 501.22(k) apply only to new product labels. Because the vast majority of animal food products that contain certified color additives are pet foods, we limit our burden estimate to reviewing labels for the use of certified color additives to pet food manufacturers subject to this regulation.

Based on A.C. Nielsen Data, we estimate that the number of animal food product units subject to § 501.22(k) for which sales of the products are greater than zero is 25,674. Assuming that the flow of new products is 10 percent per year, then 2,587 new animal food products subject to § 501.22(k) will become available on the market each year. We also estimate that there are approximately 3,120 manufacturers of pet food subject to either § 501.22(k)(1) or (k)(2). Assuming the approximately 2,587 new products are split equally among the firms, then each firm would prepare labels for approximately 0.8292 new products per year (2,587 new products/3,120 firms is approximately 0.8292 labels per firm). We expect that firms prepare the required labeling for their products in a manner that takes into account at one time all information required to be disclosed on their product labels. Based on our experience with reviewing pet food labeling, we estimate that firms would require less than 0.25 hour (15 minutes) per product to comply with the requirement to include the color additive information pursuant to § 501.22(k). The total burden of this activity is 647 hours (2,587 labels × 0.25 hour/label is approximately 647 hours). The burden for this information collection has not changed since the last OMB approval.


Leslie Kux,
Associate Commissioner for Policy.

Name of Committee: Center for Scientific Review Special Emphasis Panel on Diseases of Metabolism.
Date: March 6, 2018.
Time: 10:00 a.m. to 12:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).
Contact Person: Liliana N. Berti-Mattera, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, RM 4215, Bethesda, MD 20892, 301–827–7609, liliana.berti-mattera@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel on Neurodevelopmental Issues—Immunology, Epilepsy, Microbiome.
Date: March 9, 2018.
Time: 11:00 a.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).
Contact Person: Liliana N. Berti-Mattera, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, RM 4215, Bethesda, MD 20892, 301–827–7609, liliana.berti-mattera@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel on Conflict: Neurodevelopmental Issues—Immunology, Epilepsy, Microbiome.
Date: March 9, 2018.
Time: 10:00 a.m. to 12:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).
Contact Person: Liliana N. Berti-Mattera, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, RM 4215, Bethesda, MD 20892, 301–827–7609, liliana.berti-mattera@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel on Conflict: Neurodevelopmental Issues—Immunology, Epilepsy, Microbiome.
Date: March 9, 2018.
Time: 1:00 p.m. to 6:00 p.m.
DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings 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 on Drug Abuse Special Emphasis Panel; Exploiting HIV and/or Host Genomic Information to Understand HIV Compartmentalization in Individuals with Substance Use Disorders (R61/R33).

Contact Person: Natasha M. Copeland, Program Analyst, Office of Federal Advisory Committee Policy.

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