II. Information Collection Under Section 506J of the FD&C Act and Related Voluntary Collections

Based on current registration and listing data (approved under OMB control number 0910–0625), we estimate the number of respondents that will submit a notification under section 506J of the FD&C Act to be approximately 20 percent of currently registered manufacturers. Data from our Registration and Listing system indicate that there are approximately 42,000 unique FDA Establishment Identification registered manufacturers. Therefore, we estimate 8,400 respondents per year. We believe that the burden, as well as the provision of required information under section 506J of the FD&C Act—as well as additional voluntary information related to the determination (including additional issues that may impact the availability of the device, such as information about critical suppliers, potential mitigations, production capacity and market share, and notification updates)—is minimal and such information is readily available to manufacturers of the applicable devices. Therefore, we estimate the burden of this information collection to be 15 minutes or less per determination and notification.

<table>
<thead>
<tr>
<th>Activity</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Total annual responses</th>
<th>Average burden per response</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shortages data collection</td>
<td>500</td>
<td>4</td>
<td>2,000</td>
<td>0.5 (30 minutes)</td>
<td>1,000</td>
</tr>
<tr>
<td>Information collection under section 506J of the FD&amp;C Act</td>
<td>8,400</td>
<td>1</td>
<td>8,400</td>
<td>0.25 (15 minutes)</td>
<td>2,100</td>
</tr>
<tr>
<td>Additional voluntary collections related to section 506J of the FD&amp;C Act</td>
<td>8,400</td>
<td>1</td>
<td>8,400</td>
<td>0.25 (15 minutes)</td>
<td>2,100</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td>18,800</td>
<td></td>
<td>5,200</td>
</tr>
</tbody>
</table>

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

The information collection reflects a revision to add the information collection required by section 506J of the FD&C Act (as amended by section 3121 of the CARES Act) and additional voluntary collections related to section 506J of the FD&C Act to OMB control number 0910–0491.

Upon review of OMB control number 0910–0491, we note that there is a data-entry error in the RISC/ORIA Combined Information System (ROCIS) for a previous information collection approval on February 3, 2020. Currently, ROCIS lists the total burden hours for that approval as 390 hours; the correct total burden hour estimate is 520 hours. This error has carried through to the current total burden listed in ROCIS as 2,481 hours for the approval on November 24, 2020; the correct total burden hour estimate should be 2,611 hours. This error has carried through to the current total hour burden listed in ROCIS as 2,481 hours for the approval on February 3, 2020.

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 on Aging Special Emphasis Panel; Infectious Etiology of AD.
Date: June 24–25, 2021.
Time: 12:00 p.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Video Meeting).
Contact Person: Joshua Jin-Hyouk Park, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, National Institutes of Health, Gateway Building 2W200, 7201 Wisconsin Avenue, Bethesda, MD 20892, (301) 496–6208, joshua.park4@nih.gov.
(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHHS)


Miguelina Perez, Program Analyst, Office of Federal Advisory Committee Policy.
[FR Doc. 2021–11046 Filed 5–24–21; 8:45 am]
BILLING CODE 4140–01–P