are set forth in 21 CFR 314.50, and approved under OMB control number 0910–0001. This information collection supports part 315, currently approved under OMB control number 0910–0409.

Based on past submissions (human drug applications and/or new indication supplements for diagnostic radiopharmaceuticals), we estimate two submissions will be received annually. We estimate the time needed to prepare a complete application for a diagnostic radiopharmaceutical to be approximately 10,000 hours, roughly one-fifth of which, or 2,000 hours, is estimated to be spent preparing the portions of the application that would be affected by these regulations. The regulations do not impose any additional reporting burden for safety and effectiveness information on diagnostic radiopharmaceuticals beyond the estimated burden of 2,000 hours because safety and effectiveness information is already required by § 314.50 (collection of information approved under OMB control number 0910–0001). In fact, clarification in these regulations of FDA’s criteria for evaluation of diagnostic radiopharmaceuticals is intended to streamline overall information collection burdens, particularly for diagnostic radiopharmaceuticals that may have well-established, low-risk safety profiles, by enabling manufacturers to tailor information submissions and avoid unnecessary clinical studies.

FDA estimates the burden of this information collection as follows:

Table 1—Estimated Annual Reporting Burden

<table>
<thead>
<tr>
<th>21 CFR section</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Total annual responses</th>
<th>Average burden per response (in hours)</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnostic Radiopharmaceuticals—315.4, 315.5, and 315.6</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>2,000</td>
<td>4,000</td>
</tr>
</tbody>
</table>

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

Table 1 contains estimates of the annual reporting burden for the preparation of the safety and effectiveness sections of an application that are imposed by the applicable regulations. This estimate does not include time needed to conduct studies and clinical trials or other research from which the reported information is obtained.

Dated: October 27, 2017.
Anna K. Abram,
Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

For further information contact: Licensing information and copies of the patent applications listed below may be obtained by emailing the indicated licensing contact Michael Shmilovich, shmilovm@nih.gov at the National Heart, Lung, and Blood, Office of Technology Transfer and Development Office of Technology Transfer, 31 Center Drive Room 4A29, MSC2479, Bethesda, MD 20892–2479; telephone: 301–402–5579. A signed Confidential Disclosure Agreement may be required to receive copies of the patent applications.

Supplementary Information: This notice is in accordance with 35 U.S.C. 209 and 37 CFR 404 to achieve commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing. A description of the technology follows.

Endo-Cameral Closure Device

Description of Technology: Devices and methods for closing a hole in the wall of a cardiovascular structure from the inside using a self-assembling closure device. The closure device can be delivered to the subject hole from the inside of the cardiovascular chamber using a transcatheter approach. The methods are techniques involve deploying the closure device from the delivery device such that an endo-cameral portion of the closure device self-expands first to cover the hole from the inside, and then extra-cameral arms of the device are released to self-deploy against the outside of the wall by