forms that are equivalent. The State program maintains the documents and verifies records required for each standard. The information contained in the documents must be current and fit-for-use. If the State program fails to meet all program elements and documentation requirements of a standard, it develops a strategic plan which includes the following: (1) The individual element of documentation requirement of the standard that was not met, (2) improvements needed to meet the program element or documentation requirement of the standard, and (3) projected completion dates for each task.

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

<table>
<thead>
<tr>
<th>Respondent</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>State Departments of Agriculture or Health</td>
<td>42</td>
<td>1</td>
<td>42</td>
<td>750</td>
<td>31,500</td>
</tr>
</tbody>
</table>

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

The burden has been calculated as 750 hours per respondent. This burden was determined by capturing the average amount of time for each respondent to assess the current state of the program and work toward implementation of each of the 10 standards contained in MFRPS. The hours per respondent will change as accounted for in the continuing improvement and self-sufficiency of the program.

Dated: February 8, 2016.

Leslie Kux, 
Associate Commissioner for Policy. 

LOCATION: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: http://www.fda.gov/ AdvisoryCommittees/ AboutAdvisoryCommittees/ ucm408555.htm.

Contact Person: Cindy Hong, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, GIDAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the Federal Register about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency’s Web site at http://www.fda.gov/advisorycommittees/ default.htm and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

AGENDA: The committee will discuss new drug application (NDA) 207999, obeticholic acid oral tablets, submitted by Intercept Pharmaceuticals, Inc., proposed for the treatment of primary biliary cirrhosis in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA or as monotherapy in adults unable to tolerate UDCA.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background