**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
**Food and Drug Administration**  
[Docket No. FDA–2019–N–3077]

**Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Obtaining Information To Understand and Challenges and Opportunities Encountered by Compounding Outsourcing Facilities**

**AGENCY:** Food and Drug Administration, HHS.  
**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing that a collection of information entitled “Obtaining Information to Understand and Challenges and Opportunities Encountered by Compounding Outsourcing Facilities” has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Ila S. Mizrahi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, PRAStaff@fda.hhs.gov.

**SUPPLEMENTARY INFORMATION:** On December 18, 2020, the Agency submitted a proposed collection of information entitled “Obtaining Information to Understand and Challenges and Opportunities Encountered by Compounding Outsourcing Facilities” to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0883. The approval expires on January 31, 2022. A copy of the supporting statement for this information collection is available on the Internet at https://www.reginfo.gov/public/do/PRAMain.

<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>
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<td>501.22(k); labeling of color additive or lake of color additive; labeling of color additives not subject to certification.</td>
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<td>2,587</td>
<td>0.25 (15 minutes)</td>
<td>647</td>
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¹ There are no capital costs or operating and maintenance costs associated with this collection of information.