Antibody Cocktails for the Passive Immunization Component of Post-Exposure Prophylaxis.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information associated with submissions of content and format of labeling for drugs and biologics in 21 CFR 201.56 and 201.57 have been approved under OMB control number 0910–0572; the collections of information associated with submissions of investigational new drug applications in 21 CFR part 312 have been approved under OMB control numbers 0910–0014; the collections of information associated with submissions of applications for approval to market a new drug in 21 CFR part 314 have been approved under 0910–0001; the collections of information associated with the reporting and recordkeeping of postmarketing adverse drug experiences have been approved under OMB control numbers 0910–0001, 0910–0230, 0910–0291, and 0910–0645; and the collections of information associated with general licensing provisions for biologics in 21 CFR part 601 have been approved under OMB control number 0910–0338.

III. Electronic Access


Dated: July 26, 2021.

Lauren K. Roth,
Acting Principal Associate Commissioner for Policy.

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0584]

Agency Information Collection Activities; Proposed Collection; Comment Request; Pilot Survey To Develop Standardized Reporting Forms for Federally Funded Public Health Projects

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with a pilot survey to develop standardized reporting forms for capturing performance data for federally funded public health projects.

DATES: Submit either electronic or written comments on the collection of information by September 27, 2021.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before September 27, 2021. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 27, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

• Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

• Mail/Hand Delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2021–N–0584 for “Pilot Survey to Develop Standardized Reporting Forms for Federally Funded Public Health Projects administered by the Office of Regulatory Affairs (ORA).” Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management
We estimate that 400 respondents will participate under this pilot project and will submit an average of 3 to 4 reports within a single budget year (table 1). To ensure adequate reporting will be achieved over the course of this pilot, the option for a supplement or followup report is included in the estimated reporting burden; however, the need for these reports will be determined on a case-by-case basis with the FDA project manager.

![Table 1—Estimated Annual Reporting Burden](image-url)
TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

<table>
<thead>
<tr>
<th>Awardee activity</th>
<th>Number of recordkeepers</th>
<th>Number of records per recordkeeper</th>
<th>Total annual records</th>
<th>Average burden per recordkeeping</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Records related to Initial Report</td>
<td>400</td>
<td>1</td>
<td>400</td>
<td>0.5 hour (30 minutes)</td>
<td>200</td>
</tr>
<tr>
<td>Records related to Progress Reports</td>
<td>400</td>
<td>2</td>
<td>800</td>
<td>0.5 hour (30 minutes)</td>
<td>400</td>
</tr>
<tr>
<td>Records related to Supplement or Followup Report (if applicable)</td>
<td>100</td>
<td>1</td>
<td>100</td>
<td>0.5 hour (30 minutes)</td>
<td>50</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>650</td>
</tr>
</tbody>
</table>

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

Recordkeeping activities include storing and maintaining records related to submitting a request to participate in the project and compiling reports. Respondents should use current record retention capabilities for electronic or paper storage to achieve these activities. We assume it will take 0.5 hour/year to ensure the documents related to submitting a request to participate in the program are retained properly according to their existing recordkeeping policies, but no less than 3 years, as recommended by FDA (table 2).

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN ¹

<table>
<thead>
<tr>
<th>Awardee 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>Coordination with partnering entities related to Initial Report</td>
<td>300</td>
<td>2</td>
<td>600</td>
<td>8</td>
<td>4,800</td>
</tr>
<tr>
<td>Coordination with partnering entities related to Progress Reports</td>
<td>300</td>
<td>4</td>
<td>1,200</td>
<td>8</td>
<td>9,600</td>
</tr>
<tr>
<td>Coordination with partnering entities related to Supplement or Followup Report (if applicable)</td>
<td>100</td>
<td>2</td>
<td>200</td>
<td>8</td>
<td>1,600</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>16,000</td>
</tr>
</tbody>
</table>

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1216]

Electronic Study Data Submission; Data Standards; Technical Rejection Criteria for Study Data Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration’s (FDA or Agency) Center for Biologics Evaluation and Research (CBER) and Center for Drug Evaluation and Research (CDER) are announcing the effective date for Electronic Common Technical Document (eCTD) validations referenced in FDA’s “Technical Rejection Criteria for Study Data” (TRC).

DATES: The eCTD validations will become applicable on September 15, 2021.

ADDRESSES: You may submit either electronic or written comments at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

• Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

For those pilot projects that involve a participant composed of partnering entities in the program, FDA is taking into consideration the time that partnering entities will spend coordinating with each other in a pilot project. We estimate that 300 respondents will work with their respective partnering entities and the average number of partnering entities will be 2. We assume each respondent will spend 8 hours coordinating with each partnering entity on each response for this pilot. We estimate that seven respondents will need to coordinate with an average of two partnering entities to create progress reports and the final report to submit to FDA (table 3).

Dated: July 26, 2021.

Lauren K. Roth,
Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–16192 Filed 7–28–21; 8:45 am]

BILLING CODE 4164–01–P