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, clearance 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

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: July 26, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–16175 Filed 7–28–21; 8:45 am]

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 and 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

Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Pilot Survey To Develop Standardized Reporting Forms for Federally Funded Public Health Projects

OMB Control Number 0910–NEW

This information collection supports federally funded public health projects administered by the Agency's Office of Regulatory Affairs (ORA). As part of FDA's efforts to protect the public health, we work collaboratively with State partners to enhance oversight of FDA-regulated products. Consistent with applicable regulations pertaining to federally funded programs, we currently collect information related to an awardee's progress in completing agreed-upon performance metrics 3 to 4 times a year during the performance period. Respondents to the information collection are recipients of FDA-funded projects who submit required information to FDA in free text and narrative form via portable document format (pdf). To increase our efficiency in evaluating program effectiveness and return-on-investment (ROI)/return-on-value (ROV) for the federally funded projects that we administer, we intend to develop and establish the use of digital forms that contain standardized questions to capture data elements necessary to measure/track ROI/ROV. We believe the use of standardized forms will reduce the time required by awardees in completing and submitting progress reports.

As part of the pilot, respondents will complete an initial report and progress/performance reports, which include data fields to identify the award project and contact person and directs specific questions to respondents regarding project and progress updates. Based on public feedback, we hope to revise the reports, tailoring for project specificity and purpose, to include, but not limited to, improvements, such as drop-down menu selections and potential common response indicators that will reduce time for respondents and allow us to more quickly process information and determine impacts at the Agency level. As information will be requested of actively funded projects, it may become necessary to request additional information for a particular project to complete the performance evaluation(s) in a timely manner. To ensure data is sufficient, on a case-by-case basis, FDA anticipates a need for followup questionnaire(s) to supplement the progress reports as instruments of collection are developed and fine-tuned through this effort.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Awardee activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Initial Report	400	1	400	10	4,000
Progress Reports	400	2	800	40	32,000
Supplement or Followup Report (if applicable)	100	1	100	10	1,000
Total					37,000

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

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 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

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

[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]

Awardee activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Coordination with partnering entities related to Initial Report	300	2	600	8	4,800
Coordination with partnering entities related to Progress Reports	300	4	1,200	8	9,600
Coordination with partnering entities related to Supplement or Followup Report (if applicable)	100	2	200	8	1,600
Total					16,000

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

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

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'').