tax credit (APTC) and file an accurate tax return.

DATES: Comments must be received by August 24, 2020.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted within 10 days in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number ____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the PRA, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed ICR. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this ICR including the necessity and utility of the proposed ICR for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Contents

This notice sets out a summary of the use and burden associated with the following ICR. More detailed information can be found in the collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10751 Collection of Premium Credit Data Related to COVID–19 Emergency

Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''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. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment.

Information Collection

1. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Collection of Premium Credit Data Related to COVID–19 Emergency; *Use:* The reporting requirements and data collection in the implementing regulations for the Exchanges and QHP issuers, 45 CFR parts 155 and 156, address the minimum requirements that Qualified Health Plan (QHP) issuers must meet in order to comply with provisions in the Affordable Care Act with respect to participation in the Federally-facilitated Exchange (FFE) or a State-based Exchange (SBE). CMS currently has authority under CMS–10592/OMB Control Number: 0938–1341 to collect enrollment reconciliation data from QHP issuers. However, in light of the urgent need to help individuals and small employers experiencing economic hardship to maintain continuous coverage through the COVID–19 public health emergency, CMS is adopting a policy of relaxed enforcement with respect to 45 CFR 156.80(d), 45 CFR 156.210(a), and 155.400(e) and (g) to allow QHP issuers, on a temporary basis, to offer premium credits for 2020 coverage. Internal Revenue Service (IRS) regulations require that Exchanges accurately report enrollee premiums to the IRS and to enrollees on the annual 1095–A tax form.

To comply with existing reporting requirements, QHP issuers in states with a FFE or State-based Exchange on the Federal Platform (SBE–FP) that offer these premium credits must notify CMS of the parameters of these credits using the attached template. QHP issuers offering premium credits in a state with an SBE that relies on its own eligibility and enrollment system will follow any requirements established by the SBE for reporting planned temporary premium credits. QHP issuers must submit the attached template to notify CMS of all planned temporary premium credits for FFE or SBE–FP plans no later than October 1, 2020, regardless of the month(s) to which the credit will be applied. To ensure proper allocation of Advance Payments of the Premium Tax Credit (APTC) to the portion of premium that covers essential health benefits, CMS will adjust premium and APTC amounts in its enrollment data. CMS will also report to the IRS the premium and APTC changes in the issuer-submitted template for purposes of reconciliation to premium tax credits. In accordance with the implementing regulations of the PRA at 5 CFR 1320.13, CMS is requesting emergency processing for this ICR because it cannot reasonably comply with normal clearance procedures. Upon OMB approval of this emergency clearance request, CMS will follow the normal clearance procedures.

Form Number: CMS–10751 (OMB control number: 0938–NEW); Frequency: One-time collection; *Affected Public:* Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 175; *Total Annual Responses:* 1; *Total Annual Hours:* 175. (For policy questions regarding this collection contact Anne Pesto at 410–786–3492.)

Dated: August 11, 2020.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2020–17855 Filed 8–14–20; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–0787]

Civil Money Penalties Relating to the ClinicalTrials.gov Data Bank; Guidance for Responsible Parties, Submitters of Certain Applications and Submissions to the Food and Drug Administration, and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry and other responsible parties entitled ''Civil Money Penalties Relating to the *ClinicalTrials.gov* Data Bank; Guidance

for Responsible Parties, Submitters of Certain Applications and Submissions to FDA, and FDA Staff.'' The guidance provides the current thinking of FDA's medical product Centers—the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health—regarding civil money penalties that may be assessed under the Federal Food, Drug, and Cosmetic Act (FD&C Act) for violations of the requirements to submit clinical trial registration and results information to the *ClinicalTrials.gov* data bank and certain certifications to FDA.

DATES: The announcement of the guidance is published in the **Federal Register** on August 17, 2020.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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'').

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–2018–D–0787 for ''Civil Money Penalties Relating to the *ClinicalTrials.gov* Data Bank; Guidance for Responsible Parties, Submitters of Certain Applications and Submissions to FDA, and FDA Staff.'' Received comments 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.

- 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Office of Good Clinical Practice (OGCP), Office of Clinical Policy and Programs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Patrick McNeilly, Office of Good Clinical Practice, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5172, Silver Spring, MD 20993–0002, 301–796–2941.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry and other responsible parties entitled ''Civil Money Penalties Relating to the *ClinicalTrials.gov* Data Bank; Guidance for Responsible Parties, Submitters of Certain Applications and Submissions to FDA, and FDA Staff.'' The guidance provides the current thinking of FDA's Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, and Center for Devices and Radiological Health (Center, or collectively Centers), regarding civil money penalties for responsible parties and/or submitters of certain applications and submissions to FDA regarding drug products, biological products, and device products (submitters) who violate applicable FD&C Act (21 U.S.C. 301 *et seq.*) prohibitions relating to requirements under section 402(j) of the Public Health Service Act (PHS Act) (42 U.S.C. 282(j)), including its implementing regulations in 42 CFR part 11, to submit clinical trial registration and results information to the *ClinicalTrials.gov* data bank and certain certifications to FDA.

The guidance is intended to address several questions. First, the guidance addresses how the Centers may identify whether responsible parties have failed to submit required clinical trial registration and/or results information to the *ClinicalTrials.gov* data bank or submitted false or misleading information to the data bank, and whether submitters have failed to submit the certification required by section 402(j)(5)(B) of the PHS Act to FDA or knowingly submitted a false certification to FDA. Second, the guidance addresses the circumstances under which a Center may decide to seek civil money penalties against a responsible party or submitter. Third,

the guidance addresses the procedures that apply when a Center seeks civil money penalties; and fourth, the guidance addresses the civil money penalty amounts that may be assessed for: (1) Failing to submit required clinical trial registration and/or results information to the *ClinicalTrials.gov* data bank, (2) knowingly submitting false or misleading clinical trial information to the data bank, (3) failing to submit the required certification to FDA, or (4) knowingly submitting a false certification to FDA.

In the **Federal Register** of September 21, 2018 (83 FR 47926), FDA announced the availability of the draft guidance. FDA received comments on the draft guidance and considered all comments in finalizing this guidance. FDA revised the guidance to clarify that FDA does not intend to include on its Lists of Inspectional Observations, Forms FDA 483, any inspectional observations regarding potential violations relating to the *ClinicalTrials.gov* data bank; however, information that is collected by an investigator regarding potential violations of such requirements will be included in an Establishment Inspection Report and provided to the relevant Center for further evaluation. The guidance has also been revised to make clear that, in determining whether to seek civil money penalties, FDA intends to take into consideration any corrective action taken by a responsible party or submitter after receiving a Notice of Noncompliance. The guidance further explains that FDA intends to post Notices of Noncompliance on its website and to transmit the Notices of Noncompliance to the National Institutes of Health (NIH), so NIH can include the notice regarding noncompliance required under section 402(j)(5)(E) of the PHS Act in the *ClinicalTrials.gov* data bank. The guidance also provides some limited examples of applicable clinical trials of products that potentially may pose a higher risk to human subjects or applicable clinical trials of products intended to address significant public health need. In addition, editorial changes were made to the guidance to improve clarity. The guidance announced in this notice finalizes the draft guidance dated September 21, 2018.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on civil money penalties relating to the *ClinicalTrials.gov* data bank. 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

This guidance contains no collection 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.

However, this guidance refers to previously approved collections of information. This collection of information is subject to review by OMB under the PRA. The collection of information referenced in this guidance is related to information required under section 402(j)(5)(B) of the PHS Act and has been approved under OMB control number 0910–0616.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: August 11, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–17909 Filed 8–14–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0257]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food and Drug Administration Rapid Response Surveys

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by September 16, 2020.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0500. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, 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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Food and Drug Administration Rapid Response Surveys

OMB Control Number 0910–0500—Extension

Section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355) requires that important safety information relating to all human prescription drug products be made available to FDA so that the Agency can take appropriate action to protect the public health when necessary. Section 702 of the FD&C Act (21 U.S.C. 372) authorizes investigational powers to FDA for enforcement of the FD&C Act. Under section 519 of the FD&C Act (21 U.S.C. 360i), FDA is authorized to require manufacturers to report medical device-related deaths, serious injuries, and malfunctions to FDA; to require user facilities to report device-related deaths directly to FDA and to manufacturers; and to report serious injuries to the manufacturer. Section 522 of the FD&C Act (21 U.S.C. 360l) authorizes FDA to require manufacturers to conduct postmarket surveillance of medical devices. Section 705(b) of the FD&C Act (21 U.S.C. 375(b)) authorizes FDA to collect and disseminate information regarding medical products or cosmetics in situations involving imminent danger to health or gross deception of the consumer. Section 1003(d)(2) of the FD&C Act (21 U.S.C. 393(d)(2)) authorizes the Commissioner of Food and Drugs to implement general powers (including conducting research) to carry out effectively the mission of FDA.

These sections of the FD&C Act enable FDA to enhance consumer protection from risks associated with medical products usage that are not