are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses; and

5. Assess information collection costs.

Proposed Project

Centralized Institutional Review for the CDC Expanded Access Investigational New Drug (EA-IND) for Use of Tecovirimat (TPOXX®) for Treatment of Human Non-Variola Orthopoxvirus Infections—New—Office of Science (OS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Monkeypox is a zoonosis, caused by the Orthopoxvirus (OPXV) Monkeypox virus (MPXV), and is endemic to forested areas of West and Central Africa. In humans, infection with MPXV can lead to a smallpox-like illness with fatal outcomes in up to 11% of patients without prior smallpox vaccination. Since May 2022, clusters of monkeypox cases, have been reported in 19 countries that do not normally have monkeypox, and the number of confirmed cases in the U.S. is rapidly increasing.

Tecovirimat (also known as TPOXX) is FDA-approved for the treatment of human smallpox disease caused by Variola virus in adults and children. However, its use for other orthopoxvirus infections, including monkeypox, is not approved by the FDA. CDC currently holds a non-research expanded access Investigational New Drug (EA-IND) protocol that allows for the use of tecovirimat for primary or early empiric treatment of non-variola orthopoxvirus infections, including monkeypox, in adults and children of all ages.

FDA regulations require that an Institutional Review Board (IRB) review, approve and maintain oversight of the activities under the EA-IND as set forth in 21 CFR parts 50, 56, and 312. The CDC IRB is positioned to serve as the central IRB for review and approval of the EA-IND consistent 21 CFR 56.114. This arrangement allows facilities to use or rely on the CDC IRB for centralized review and approval for this protocol in place of review by the site-specific IRB to help reduce duplication of effort, delays, and increased expenses. Any facility that receives tecovirimat for treatment of orthopoxvirus infection under the EA-IND may elect to rely on the CDC IRB to meet FDA's regulatory requirements.

The IRB review is required by FDA under the CDC's approved EA-IND. Therefore, CDC must maintain records of which facilities have elected to rely on the CDC IRB for centralized review and which facilities elect to obtain IRB review on their own.

CDC will use collected data to track and document the institutions relying on the CDC IRB so they can provide tecovirimat (TPOXX) treatment to their patients with monkeypox under the EA-IND.

CDC requests OMB approval for an estimated 13,333 annual burden hours. There is no cost to respondents other than their time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number responses per respondent	Average burden per response (in hrs.)	Total burden (in hrs.)
Hospital/IRB Administrators	CDC IRB Authorization Agreement (for review).	5,000	1	1	5,000
Hospital/IRB Administrators	CDC IRB Authorization Agreement (for completion and submission to CDC.	5,000	10	10/60	8,333
Total					13,333

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2022–17986 Filed 8–19–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0893]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Center for Devices and Radiological Health Appeals Processes

AGENCY: Food and Drug Administration, 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 21, 2022.

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 0910–0738. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–45, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *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.

Center for Devices and Radiological Health Appeals Processes

OMB Control Number 0910–0738—Extension

This information collection supports implementation of recommendations found in FDA guidance. As discussed in the document entitled ''Guidance for

Industry and Food and Drug Administration Staff; Center for Devices and Radiological Health (CDRH) Appeals Processes'' (July 2019), there are various processes by which appeals requests regarding review of decisions or actions by CDRH may be submitted to the Agency. The guidance is available for download from our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/center-devices-and-radiological-health-cdrh-appeals-processes.* The guidance document provides general format and content recommendations in this regard, discusses applicable regulations with regard to the timing of such submissions, and describes the collection of information not expressly specified under existing regulations such as the submission of the request for review, minor clarifications as part of the request, and supporting information. While CDRH already possesses in the administrative file the information that would form the basis of a decision on a matter under appeal, the submission of information as recommended in the guidance regarding the appeal request itself, as well as data and information relied on by the requestor in the appeal, will help facilitate timely resolution of the decision under review. We are accounting for burden respondents may incur as a result of these Agency recommendations in this collection request. Additional information about the CDRH appeals process is described in the companion guidance entitled ''Center for Devices and Radiological Health (CDRH) Appeals Processes: Questions and Answers About 517A—Guidance for Industry and Food and Drug Administration Staff'' (March 2020), also available for download from our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/center-devices-and-radiological-health-cdrh-appeals-processes-questions-and-answers-about-517a.*

In the **Federal Register** of February 18, 2022 (87 FR 9365) we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

CDRH Appeals Processes: Guidance for Industry and FDA Staff	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Recommended format and content elements	35	1	35	8	280

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

We estimate 35 requests will be submitted annually to review decisions and actions by CDRH employees, we attribute one respondent per submission, and we assume each request will take 8 hours to prepare. Based on our evaluation of the information collection since last OMB approval, we have made no adjustments to the currently approved burden estimate.

Dated: August 17, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–18065 Filed 8–19–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–2544]

Agency Information Collection Activities; Proposed Collection; Comment Request; Current Good Manufacturing Practice; Quality System Regulation

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 recordkeeping requirements related to the medical devices current good manufacturing practice (CGMP) quality system (QS) regulation (CGMP/QS regulation).

DATES: Either electronic or written comments on the collection of information must be submitted by October 21, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 21, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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