prevent the potential spread of the communicable disease, provided that such measures do not affect the airworthiness of the aircraft or the safety of flight operations.

(b) The pilot in command of an aircraft operated by an airline who reports in accordance with paragraph (a) of this section shall be deemed to satisfy the reporting obligation under 42 CFR 70.4.

For the purposes of these regulations, ill person means an individual who:

(1) Has a fever (a measured temperature of 100.4 °F [38 °C] or greater, or feels warm to the touch, or gives a history of feeling feverish) accompanied by one or more of the following: Skin rash, difficulty breathing, persistent cough, decreased consciousness or confusion of recent onset, new unexplained bruising or bleeding (without previous injury), persistent diarrhea, persistent vomiting (other than air sickness), headache with stiff neck, appears obviously unwell; or

(2) Has a fever that has persisted for more than 48 hours; or

(3) Has symptoms or other indications of communicable disease, as the CDC may announce through posting of a notice in the **Federal Register**.

Control of disease transmission within the United States is largely considered to be the province of State and local health authorities, with Federal assistance being sought by those authorities on a cooperative basis, without application of Federal regulations. The regulations at 42 CFR part 70 were developed to facilitate Federal action in the event of large outbreaks requiring a coordinated effort involving several States, or in the event in inadequate local control. While it is not known whether, or to what extent, situations may arise in which these regulations would be invoked, contingency planning for domestic emergency preparedness is not uncommon. If a domestic emergency occurs, the reporting and record keeping requirements contained in the regulations will be used by CDC to carry out quarantine responsibilities as required by law, specifically, to prevent the spread of communicable diseases from one State or possession into any other State or possession.

The data collected under 70.4 and 70.11 is also a critical part of CDC's routine and emergency response operations. It involves the collection of reports of illnesses that occur aboard domestic flights or maritime voyages within the U.S. For routine reports of illness aboard domestic voyages airplane captains will continue to report electronically (*e.g.,* verbally via radio to Air Traffic Control or the airlines' points of contact [*e.g.,* Operations Center, Flight Control, Airline Station Manager]). Masters of maritime vessels engaged in interstate travel may report via email or other electronic method.

The reporting of required and requested signs and symptoms of disease outlined above, as well as any death, is the minimum necessary to meet statutory and regulatory obligations, and is consistent with International Civil Aviation Organization (ICAO) standards for aircraft.

CDC anticipates certain cost burdens to respondents and record keepers due to the requirements. These costs fall into the following categories:

For reports of death or communicable disease made by a pilot in command of an aircraft, or a master of a vessel or person in charge of a conveyance engaged in interstate traffic, the requested burden is approximately 186 hours. This total is estimated from approximately 1,600 domestic reports of death or communicable disease a year, 1,400 being from aircrafts, and approximately 200 from other conveyances (water vessels, buses, or trains) with an average burden of seven minutes per report. There is no standard form for reporting to CDC or the health departments and 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 of responses per respondent	Average burden per response (in hours)
Pilot in command	42 CFR 70.11 Report of death or illness onboard aircraft operated by airline (No Form).	1,400	1	7/60
Master of vessel or person in charge of conveyance.	42 CFR 70.4 Report by the master of a vessel or person in charge of conveyance of the incidence of a communicable. disease occurring while in interstate travel (No form)	200	1	7/60

Jeffrey M. Zirger,

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

[FR Doc. 2022–13889 Filed 6–28–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10691]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection 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.

DATES: Comments must be received by August 29, 2022.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted 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 website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

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

SUPPLEMENTARY INFORMATION:

Contents

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

CMS–10691 Data Request and Attestation for PDP Sponsors

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. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title:* Data Request and Attestation for PDP Sponsors; *Use:* Section 50354 of the BBA requires that the Secretary establish a process for PDP sponsors to submit a request for standardized extracts of claims data for their enrollees. In addition, Section 50354 of the BBA provides for a number of purposes and limitation for the use of the claims data and also permits the Secretary to establish other limitations necessary to protect the identity of individuals entitled to or enrolled in Medicare, and to protect the security of personal health information

This information collection request allows a PDP sponsor to submit a request to CMS for claims data for its enrollees and to attest that it will adhere to the permitted uses and limitations on the use of the Medicare claims data that are listed in 42 CFR 423.153(g)(3) and After requesting claims data for its enrollees and attesting to the permitted uses and limitations of Medicare claims data, PDP sponsors are required to complete some basic on-boarding activities before gaining access to Medicare claims data using the Part A and B Claims Data to Part D Sponsors (AB2D) API. *Form Number:* CMS–10691 (OMB Control Number: 0938–1371); *Frequency:* Annually; *Affected Public:* Private Sector, Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 210*; Number of Responses:* 210 *Total Annual Hours:* 39. (For policy questions regarding this collection contact Gaare, Kari A. at 410–786–8612.)

Dated: June 23, 2022.

William N. Parham, III,

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

[FR Doc. 2022–13804 Filed 6–28–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–E–0449]

Determination of Regulatory Review Period for Purposes of Patent Extension; DANYELZA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for DANYELZA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by August 29, 2022. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by December 27, 2022. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

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 August 29, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 29, 2022. 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