

threats, both domestically and internationally to its components, which are as follows:

- Center for Global Health (CBB)
- Center for Preparedness and Response (CBC)
- Center for State, Tribal, Local and Territorial Support (CBD)
- Office of Minority Health and Health Equity (CBE)

- Deputy Director for Public Health Science and Surveillance (CP): The Deputy Director for Public Health Science and Surveillance leads, promotes, and facilitates science, surveillance, standards and policies to reduce the burden of diseases in the United States and globally to its components, which are as follows:

- National Center for Health Statistics (CPC)
- Center for Surveillance, Epidemiology, and Laboratory Services (CPN)
- Office of Science (CPP)
- Office of Laboratory Science and Safety (CPQ)

- *Deputy Director for Non-Infectious Diseases (CU)*: The Deputy Director for Non-Infectious Diseases reduces the burden of non-infectious diseases, injuries, birth defects, disabilities and environmental health hazards to its components, which are as follows:

- National Center on Birth Defects and Developmental Disabilities (CUB)
- National Center for Chronic Disease Prevention and Health Promotion (CUC)
- National Center for Environmental Health/Agency for Toxic Substances and Disease Registry (CUG)
- National Center for Injury Prevention and Control (CUH)

- *Deputy Director for Infectious Diseases (CV)*: Deputy Director for Infectious Diseases leads, promotes, and facilitates science, programs, and policies to reduce the burden of infectious disease in the United States and globally and its components, which are as follows:

- National Center for Immunization and Respiratory Diseases (CVG)
- National Center for Emerging and Zoonotic Infectious Diseases (CVL)
- National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention

IV. *Delegations of Authority*: All delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegation, provided they are consistent with this reorganization.

Authority: 44 U.S.C. 3101.

Dated: August 17, 2018.

Alex M. Azar II,
Secretary.

[FR Doc. 2018–20835 Filed 9–24–18; 8:45 am]

BILLING CODE 4160–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–18–0891]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled World Trade Center Health Program Enrollment, Treatment, Appeals & Reimbursement to the Office of Management and Budget (OMB) for review and approval. CDC previously published a “Proposed Data Collection Submitted for Public Comment and Recommendations” notice on May 11, 2018, to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who 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 submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and

instruments, call (404) 639–7570 or send an email to omb@cdc.gov. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

World Trade Center Health Program Enrollment, Treatment, Appeals & Reimbursement (OMB Control No. 0920–0891, Expires 09/30/2018)—Revision—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

NIOSH seeks to request OMB approval to revise the currently approved information collection activities that support the World Trade Center (WTC) Health Program. The James Zadroga 9/11 Health and Compensation Act of 2010 (Pub. L. 111–347, as amended by Pub. L. 114–113) created the WTC Health Program to provide medical monitoring and treatment benefits to eligible individuals affected by the terrorist attacks on September 11, 2001. Eligible individuals include firefighters and related personnel, law enforcement officers, and rescue, recovery, and cleanup workers who responded to the attacks in New York City, at the Pentagon, and in Shanksville, Pennsylvania (responders), and to eligible persons who were present in the dust or dust cloud on September 11, 2001, or who worked, resided, or attended school, childcare, or adult daycare in the New York City disaster area (survivors).

This request also seeks to incorporate information collection previously approved under the World Trade Center Health Program Petition for the Addition of a New WTC-Related Health Condition for Coverage under the World Trade Center (WTC) Health Program (OMB No. 0920–0929, expiration date 7/31/2018), which has been discontinued. The revision of OMB No. 0920–0891 will provide a comprehensive summary of information collection needed to administer the World Trade Center Health Program.

Since its inception in 2011, the WTC Health Program has been approved to collect information from applicants and Program members (enrolled WTC responders and survivors) concerning eligibility and enrollment, appointment of a designated representative, medical care, travel reimbursement, and appeal

of adverse Program decisions. The WTC Health Program is also currently approved to collect information from Program medical providers, including health condition certification requests and pharmaceutical claims. The WTC Health Program has determined that some existing forms need to be updated, and new information collections related to a recent rulemaking should be added.

Changes to WTC Health Program regulations in 42 CFR part 88 will require the extension of existing information collections. Specifically, 42 CFR 88.13 establishes procedures for the appeal of Program decisions to disenroll Program members and deny enrollment to applicants. Appeals of enrollment denial decisions, which include the submission of appeal request letters, are currently approved; the Program proposes to extend this information collection to account for the burden of requests for appeal of disenrollment decisions. Of the over 70,000 Program members, we expect that 0.014 percent (10) will be subsequently disenrolled from the Program. Of those, we expect that 30 percent (3) will appeal the disenrollment decisions. We estimate that the disenrollment appeal requests will take no more than 0.5 hours per respondent. The annual burden estimate is 2 hours (rounded).

Section 42 CFR 88.21 establishes procedures for the appeal of WTC Health Program decisions to decertify a WTC-related health condition, deny certification, and deny treatment authorization. Appeals of health condition certification denials and treatment authorization denials, which include the submission of appeal request letters, are currently approved; the Program proposes to extend this information collection to account for the burden of requests for appeal of

decertification decisions. The information collection will also be expanded to allow Program members to provide additional information and/or an oral statement. Of the estimated 51,472 Program members who have at least one health condition certification, we estimate that 0.02 percent (10) will be decertified, and 50 percent (5) of those will appeal a decertification. We estimate that the appeal request letter will take no more than 0.5 hours per respondent. Providing additional information and/or an oral statement will take no more than one hour per respondent. The annual burden estimate for decertification appeals is 8 hours.

We further estimate that Program members request certification for 20,000 health conditions each year. Of those 20,000, we estimate that one percent (200) of certification requests are denied by the WTC Health Program. We also expect that 30 percent of denied certifications, or 60 individuals, will be appealed. We estimate that the appeals letter takes no more than 30 minutes and providing additional information and/or an oral statement will take no more than one hour. The burden estimate for certification denial appeals is 90 hours.

In addition, of the projected 51,472 Program members who receive medical care, we estimate that 0.05 percent (26) will appeal a determination by the WTC Health Program that the treatment being sought is not medically necessary. We estimate that the appeals letter will take no more than 30 minutes and providing additional information and/or an oral statement will take no more than one hour. The burden estimate for treatment authorization denial appeals is 39 hours.

Finally, 42 CFR 88.23 establishes procedures for the appeal of a WTC

Health Program decision to deny reimbursement to a Program medical provider for treatment determined not to be medically necessary. Accordingly, the Program proposes the addition of information collected in the appeal request. We estimate that of the nearly 52,000 Program providers, we estimate that 1.15 percent (600) annually will be denied reimbursement for treatment found to be not medically necessary or in accordance with treatment protocols, and will appeal the decision. We estimate that the appeal letter will take no more than 0.5 hours to compile. The burden estimate for treatment reimbursement denial appeals is 300 hours.

The revision request also includes the addition of a new form to allow applicants and Program members to grant permission to share information with a third person about an individual's application or case. We estimate that 30 applicants and members will submit a Health Insurance Portability and Accountability Act (HIPAA) Release Form annually. The form will take no longer than 0.25 hours to complete. The burden estimate for the HIPAA Release form is 8 hours.

The total estimated annualized burden hours are 14,063, an increase of 469 hours from the previously approved estimate of 13,594 hours. The revised estimate includes forms that have not been modified; changes due to the appeals processes authorized by 42 CFR 88.21 and 42 CFR 88.23; inclusion of the new HIPAA Release Form; incorporation of a form previously approved under OMB No. 0920-0929; and miscellaneous actions. The revision request provides a detailed summary of each change and its impact on the burden estimate.

BACKGROUND AND BRIEF DESCRIPTION

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
FDNY Responder	World Trade Center Health Program FDNY Responder Eligibility Application.	45	1	30/60
General Responder	World Trade Center Health Program Responder Eligibility Application (Other than FDNY).	2,475	1	30/60
Pentagon/Shanksville Responder	World Trade Center Health Program Pentagon/Shanksville Responder.	630	1	30/60
WTC Survivor	World Trade Center Health Program Survivor Eligibility Application (all languages).	1,350	1	30/60
General responder	Clinic Selection Postcard for new general responders in NY/NJ to select a clinic.	2,475	1	15/60
Program Medical Provider	Physician Request for Certification (WTC-3)	20,000	1	30/60
Responder (FDNY and General Responder)/Survivor.	Denial Letter and Appeal Notification—Enrollment	45	1	30/60
Responder (FDNY and General Responder)/Survivor.	Disenrollment Letter and Appeal Notification—Enrollment.	3	1	30/60

BACKGROUND AND BRIEF DESCRIPTION—Continued

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Responder (FDNY and General Responder)/Survivor.	Decertification Letter and Appeal Notification—Health Condition.	5	1	1.5
Responder (FDNY and General Responder)/Survivor.	Denial Letter and Appeal Notification—Health Condition Certification.	60	1	1.5
Responder (FDNY and General Responder)/Survivor.	Denial Letter and Appeal Notification—Treatment Authorization.	26	1	1.5
Responder (FDNY and General Responder)/Survivor.	WTC Health Program Medical Travel Refund Request.	10	1	10/60
Program Members	Designated Representative Form	30	1	15/60
Program Member	HIPAA Release Form to allow the sharing of member information with a third party.	30	1	15/60
Pharmacy	Outpatient prescription pharmaceuticals	150	261	1/60
Program Medical Provider	Reimbursement Denial Letter and Appeal Notification—Providers.	600	1	30/60
Responder/Survivor/Advocate (physician).	Petition for the addition of health conditions	60	1	1

Jeffrey M. Zirger,

Acting Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3404]

Agency Information Collection Activities; Proposed Collection; Comment Request; Generic Drug User Fee Cover Sheet

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) 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 collection of information using Form FDA 3794, entitled “Generic Drug User Fee Cover Sheet.”

DATES: Submit either electronic or written comments on the collection of information by November 26, 2018.

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 November 26, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 26, 2018. 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–2018–N–3404 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Generic Drug User Fee Cover Sheet.” 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.

- **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