

ESTIMATE OF ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Clinic	Demographic Clinical Data Form 1	30	240	11/60
Laboratory	Antimicrobial Susceptibility Testing Form 2 ...	5	1,452	1
	Control Strain Susceptibility Testing Form 3	5	48	12/60

Leroy A. Richardson,

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

Centers for Disease Control and Prevention

[30Day-16-0488]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (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. Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

Restrictions on Interstate Travel of Persons (42 CFR part 70) (OMB Control No. 0920-0488, expiration, 3/31/2016)—Revision—Division of Global Migration and Quarantine, National Center for Emerging Zoonotic and Infectious Diseases, Centers for Disease Control and Prevention (CDC).

Background and Brief Description

This revision to an existing information collection request is intended to ensure that CDC can continue collect pertinent information related to communicable disease or deaths that occur aboard conveyances during interstate travel within the United States, as authorized under 42 Code of Federal Regulations (CFR) part 70. Additionally, CDC is requesting approval to use the Passenger Locator Form in the event that travelers on domestic flights within the United States need to be contacted for public health follow-up.

The intended use of the information is to ensure that CDC can assess and respond to reports of communicable disease or death that occur on conveyances engaged in interstate travel, and assist state and local health authorities if an illness or death occurs that poses a risk to public health. Generally, the primary source of this information is aircraft and travelers moving within the United States.

This revision makes several modification to this information collection. They are as follows: In current practice, CDC does not process applications for travel permits using the Restriction On Travel Of Persons Multipurpose Application Form Under

the Provisions of 42 CFR part 70 (aka Ill Person Travel Permit); therefore the information collections under 42 CFR 70.3, Application to the State of destination for a permit, Copy of material submitted by applicant and permit issued by State health authority (Attending physician), and Copy of material submitted by applicant and permit issued by State health authority (State health authority) are being removed. Similarly, information collections under 42 CFR 70.5, Application for a permit to move from State to State while in the communicable period (Attending physician) and Application for a permit to move from State to State while in the communicable period (Traveler) are also being removed. The issuance of travel restrictions is a collaborative process between public health partners, e.g. state health departments, the Department of Homeland Security, and CDC. There is no standardized collection of information involved. This change results in the removal of the information collections under 42 CFR 70.3 and 70.5 from the list of information collections as well as the removal of the associated burden. Reports of communicable disease or death from domestic conveyances are almost always submitted electronically to meet requirements of 42 CFF 70.4, so the current hard copy Master of Vessel or Conveyance Illness Report, which was constructed to be used by masters of vessels to comply with 42 CFR 70.4, has been rendered obsolete. In addition, CDC has issued guidance stating that reports to CDC, instead of local health authorities, regarding domestic reports of communicable disease or death on board conveyances meet the requirements of the regulation; therefore, information collections related to copies of the report sent by masters of vessels to state health departments are no longer necessary. The only remaining information collection under 42 CFR 70.4 is 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.

CDC is also requesting an adjustment to the burden associated with reports of communicable disease or death from domestic conveyances. CDC is reducing the burden from 15 minutes per report to 7 minutes. This is due to the facilitation of reporting using electronic means, *i.e.* Air Traffic Control and the Domestic Events Network for domestic flights, rather than the hard copy Master of Vessel or Conveyance Illness Report.

Finally, CDC is requesting the addition of the Passenger Locator Form to this information collection. CDC currently has approval to collect the Passenger Locator Form from travelers aboard international flights under OMB Control Number 0920-0134. CDC is requesting approval to collect passenger contact and locating information for travelers aboard domestic flights within the United States.

The resulting change in burden is a reduction of 3,611 hours.

Estimated Annualized Burden Hours

CDC anticipates this information collection will result in 90 total burden hours from 1,000 respondents. There is no burden to respondents other than the time required to complete and send the requested information to CDC. The estimated annualized burden is 90 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Master of a vessel or person in charge of a 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.	200	1	7/60
Traveler	Passenger Locator Form	800	1	5/60

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 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 Nos. FDA-2014-E-0308 and FDA-2014-E-0309]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for FULYZAQ 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 drug product.

DATES: Anyone with knowledge that any of the dates as published (in the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by February 8, 2016.

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 June 7, 2016. See “Petitions” in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://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 <http://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):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, 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 Nos. FDA-2014-E-0308 and FDA-2014-E-0309 for “Determination of Regulatory Review Period for Purposes of Patent Extension; FULYZAQ.” Received comments will be placed in the dockets and, except for those submitted as “Confidential Submissions,” publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management 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