

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

Report of Illness or Death: Interstate Travel of Persons (42 CFR part 70)—Revision—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Section 361 of the Public Health Service Act (42 U.S.C. 264) authorizes

the Secretary of the Department of Health and Human Services to make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States, or from one State or possession into any other State or possession. CDC administers regulations pertaining to interstate control of communicable diseases (42 CFR part 70), and sections 42 CFR parts 70.4 and 70.11 include requirements for reports of ill persons or death if occurring during interstate travel.

The intended use of the information is to ensure that CDC can assess and respond to reports of ill persons 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 traveling within the United States.

In 2017, CDC finalized the Control of Communicable Disease regulations (42 CFR 70 and 71). With this new

provision, CDC divided the total anticipated reporting burden between 70.11 and 70.4 in the accompanying Paperwork Reduction Act section of the rule, assuming that aircraft would report most cases of ill people and deaths to CDC, with some airlines and other conveyances reporting still to local public health authorities. For reports of ill persons or death on a conveyance engaged in interstate traffic, the requested burden is approximately 23 hours. This total is estimated from 200 respondents submitting domestic reports of death or communicable disease a year, with an average burden of 7 minutes per report. The only requested change to the approved data collection is a change in title from “Restriction on Travel of Persons (42 CFR part 70)” to “Report of Illness or Death: Interstate Travel of Persons (42 CFR part 70)”. This results in two rows in the burden table, but with no additional burden. The estimated annual Burden Hours are 23. There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

| Type of respondents | 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. | 190 | 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. | 10 | 1 | 7/60 |

Jeffrey M. Zirger

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

[FR Doc. 2018-23861 Filed 10-31-18; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0873]

Agency Information Collection Activities; Proposed Collection; Comment Request; Bar Code Label Requirement for Human Drug and Biological Products

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 bar code label requirements for human drug and biological products.

DATES: Submit either electronic or written comments on the collection of information by December 31, 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 December 31, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time

at the end of December 31, 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-2012-N-0873 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Bar Code Label Requirement for Human Drug and Biological Products.” 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 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.gpo.gov/fdsys/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.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrahi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St, North Bethesda, MD 20852, 301-796-7726, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: 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. “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 (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4)

ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Bar Code Label Requirement for Human Drug and Biological Products

OMB Control Number 0910-0537—Extension

In the **Federal Register** of February 26, 2004 (69 FR 9120), FDA issued a final rule that requires human drug product and biological product labels to have bar codes. Specifically, the final rule requires bar codes on most human prescription drug products and on over-the-counter (OTC) drug products that are dispensed under an order and commonly used in health care facilities. It also requires machine-readable information on blood and blood components. For human prescription drug products and OTC drug products that are dispensed under an order and commonly used in health care facilities, the bar code must contain the national drug code number for the product. For blood and blood components, the final rule specifies the minimum contents of the label in a format that is machine readable and approved for use by the Director, Center for Biologics Evaluation and Research. We believe that the final rule helps reduce the number of medication errors in hospitals and other health care settings by allowing health care professionals to use bar code scanning equipment to verify that the right drug (in the right dose and right route of administration) is being given to the right patient at the right time.

Although most of the information collections created by the final rule have now been incorporated in OMB approved information collections supporting the applicable regulations, respondents to the collection may continue to seek an exemption from the bar code label requirement under § 201.25(d) (21 CFR 201.25(d)). Section 201.25(d) requires submission of a written request for an exemption and describes the information that must be included in such a request. Based on the number of exemption requests we have received previously, we estimate that approximately 2 exemption requests will be submitted annually and each exemption request will require 24 hours to complete. This results in an annual reporting burden of 48 hours, as reflected in table 1.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

| 21 CFR section | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|------------------------|-----------------------|------------------------------------|------------------------|-----------------------------|-------------|
| 21 CFR 201.25(d) | 2 | 1 | 2 | 24 | 48 |

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

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: October 29, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–23910 Filed 10–31–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel Review of NIEHS K08, K23, K24, and K25 Applications.

Date: November 13, 2018.

Time: 11:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Environmental Health Science, Keystone Building, 530 Davis Drive, Room 2164, Research Triangle Park, NC 27709 (Telephone Conference Call).

Contact Person: Janice B. Allen, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, National Institute of Environmental Health Science, 530 Davis Drive, Room 3170 B, Research Triangle Park, NC 27709, (919) 541–7556, allen9@niehs.nih.gov.

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel Review of NIEHS Revolutionizing Innovative, Visionary

Environmental Health Research (RIVER) APPLICATIONS.

Date: November 15, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Marriott Chapel Hill, 01 Erwin Road, Chapel Hill, NC 27514.

Contact Person: Leroy Worth, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, National Institute of Environmental Health Sciences, P.O. Box 12233, MD EC–30/ Room 3171, Research Triangle Park, NC 27709, 919/541–0670, worth@niehs.nih.gov.

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel NIH/NIEHS E-Learning for HAZMAT and Emergency Response.

Date: November 19, 2018.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: NIEHS/National Institutes of Health Keystone Building, 530 Davis Drive, Room 2164, Research Triangle Park, NC 27709 (Telephone Conference Call).

Contact Person: Laura A. Thomas, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, National Institute of Environmental Health Sciences, Research Triangle Park, NC 27709, 919–541–2824, laura.thomas@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: October 26, 2018.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–23856 Filed 10–31–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel; Shared Instrumentation: Interdisciplinary Molecular Sciences and Technologies (S10).

Date: November 27, 2018.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Alexander Gubin, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6046B, MSC 7892, Bethesda, MD 20892, 301–408–9655, gubina@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Nephrology Small Business Review.

Date: November 27, 2018.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Atul Sahai, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2188, MSC 7818, Bethesda, MD 20892, 301–435–1198, sahaia@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Chemosensory Systems, Neurotoxicology and Alcohol.

Date: November 27, 2018.