

Evaluation and Research, (HFD-860), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4132, Silver Spring, MD 20993, 301-796-1697.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI) Drug Products—Quality Considerations." This guidance describes points to consider to help ensure product quality and performance for MDIs and DPIs. It describes chemistry, manufacturing, and controls information recommended for inclusion in new drug applications (NDAs) and abbreviated new drug applications (ANDAs); however, the principles are applicable to products used during clinical trials and over the product lifecycle, as well. It also provides recommendations on certain aspects of labeling for NDA and ANDA MDI and DPI products. FDA previously published a draft guidance on this topic on November 13, 1998. The present guidance is a revision of the previous draft, updated to reflect current standards and requirements to enhance understanding of development approaches for these products consistent with the quality by design paradigm.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on "Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI) Drug Products—Quality Considerations." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This guidance includes information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information referenced in this guidance that are related to the burden for the submission of investigational new drug applications are covered under 21 CFR part 312 and have been approved under OMB control number 0910-0014. The collections of information referenced in this guidance that are related to the burden for the submission of new drug applications that are covered under 21 CFR part 314

have been approved under OMB control number 0910-0001. The submission of prescription drug product labeling under 21 CFR 201.56 and 201.57 is approved under OMB control number 0910-0572.

The guidance also discusses labeling for MDI and DPI drug products, and references 21 CFR part 201. In the **Federal Register** of December 18, 2014 (79 FR 75506), FDA published its proposed rule on the electronic distribution of prescribing information for human prescription drugs, including biological products. In Section VII, "Paperwork Reduction Act of 1995," FDA estimated the burden to design, test, and produce the label for a drug product's immediate container and outer container or package, as set forth in 21 CFR part 201, including §§ 201.10, 201.100(b), and other sections in subpart A and subpart B.

III. Electronic Access

Persons with access to the internet may obtain the document at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: April 13, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-08200 Filed 4-18-18; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

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

The meeting 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 Allergy and Infectious Diseases Special Emphasis Panel; NIAID Clinical Trial Implementation Grant (R01).

Date: May 11, 2018.

Time: 11:00 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: J. Bruce Sundstrom, Ph.D., Scientific Review Officer Scientific Review Program, Division of Extramural Activities, Room 3G11A, National Institutes of Health/NIAID, 5601 Fishers Lane, MSC 9823, Bethesda, MD 20892-9823, 240-669-5045, sundstromj@niaid.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: April 13, 2018.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018-08171 Filed 4-18-18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

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

The meeting 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; Global Noncommunicable Diseases and Injury Across the Lifespan: Exploratory Research.

Date: April 25, 2018.

Time: 11:00 a.m. to 1:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Fungai Chanetsa, MPH, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3135, MSC 7770 Bethesda, MD 20892, 301-408-9436, fungai.chanetsa@nih.hhs.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: April 13, 2018.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–08170 Filed 4–18–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

Revision of Agency Information Collection Activity Under OMB Review: Crew Member Self-Defense Training—Registration and Evaluation

AGENCY: Transportation Security Administration, DHS.

ACTION: 30-Day notice.

SUMMARY: This notice announces that the Transportation Security Administration (TSA) has forwarded the Information Collection Request (ICR), Office of Management and Budget (OMB) control number 1652–0028, abstracted below to OMB for review and approval of a revision of the currently approved collection under the Paperwork Reduction Act (PRA). The ICR describes the nature of the information collection and its expected burden. The collection involves requesting information from flight and cabin crew members of air carriers to participate in voluntary advanced self-defense training provided by TSA. Each crew member will also be required to complete an electronic Injury Waiver Form. Additionally, each participant is asked to complete an anonymous course evaluation at the conclusion of the training.

DATES: Send your comments by May 21, 2018. A comment to OMB is most effective if OMB receives it within 30 days of publication.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, OMB. Comments should be addressed to Desk Officer, Department of Homeland Security/TSA, and sent via electronic mail to dhsdeskofficer@omb.eop.gov.

FOR FURTHER INFORMATION CONTACT: Christina A. Walsh, TSA PRA Officer, Office of Information Technology (OIT), TSA–11, Transportation Security

Administration, 601 South 12th Street, Arlington, VA 20598–6011; telephone (571) 227–2062; email TSAPRA@tsa.dhs.gov.

SUPPLEMENTARY INFORMATION: TSA published a **Federal Register** notice, with a 60-day comment period soliciting comments, of the following collection of information on December 12, 2017, 82 FR 58433.

Comments Invited

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The ICR documentation will be available at <http://www.reginfo.gov> upon its submission to OMB. Therefore, in preparation for OMB review and approval of the following information collection, TSA is soliciting comments to—

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

(2) Evaluate the accuracy of the agency's estimate of the burden;

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

(4) Minimize the burden of the collection of information on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Consistent with the requirements of Executive Order (E.O.) 13771, Reducing Regulation and Controlling Regulatory Costs, and E.O. 13777, Enforcing the Regulatory Reform Agenda, TSA is also requesting comments on the extent to which this request for information could be modified to reduce the burden on respondents.

Information Collection Requirement

Title: Crew Member Self-Defense Training—Registration and Evaluation.

Type of Request: Revision of a currently approved collection.

OMB Control Number: 1652–0028.

Forms(s): “Web enabled Registration Form”; “Injury Waiver Form”; “Attendance Roster”; “Electronic Feedback Tab.”

Affected Public: Flight and cabin crew members on passenger and cargo flights.

Abstract: TSA is seeking a revision of the ICR, currently approved under OMB control number 1652–0028, to continue compliance with a statutory mandate.

Under 49 U.S.C. 44918(b), TSA is required to develop and provide a voluntary advanced self-defense training program for flight and cabin crew members of U.S. air carriers providing scheduled passenger air transportation.

TSA currently collects biographical information from crew members to confirm their eligibility to participate in this training program and to confirm their attendance. TSA confirms the eligibility of the participant by contacting the participant's employer, and confirms attendance by comparing the registration information against a sign-in sheet provided in the classroom.

TSA is making a number of revisions to this ICR. First, TSA is changing the name of the collection from “Flight Crew Self-Defense Training-Registration and Evaluation” to “Crew Member Self-Defense Training-Registration and Evaluation.” Furthermore, TSA has expanded the program to allow voluntary participation by air carriers providing cargo air transportation. Also, TSA will no longer collect the last four digits of the SSN from crew members and will update the attendance roster to add a “training complete” column and remove the “Day 1–3” and “2nd ID #” columns. In addition, TSA will include an electronic Injury Waiver Form. Finally, TSA will replace the evaluation form with an electronic feedback tab.

Number of Respondents: 3,400.

Estimated Annual Burden Hours: An estimated 595 hours annually.

Dated: April 13, 2018.

Christina A. Walsh,

TSA Paperwork Reduction Act Officer, Office of Information Technology.

[FR Doc. 2018–08162 Filed 4–18–18; 8:45 am]

BILLING CODE 9110–05–P

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

Extension of Agency Information Collection Activity Under OMB Review: Law Enforcement Officers Flying Armed Training

AGENCY: Transportation Security Administration, DHS.

ACTION: 30-Day notice.

SUMMARY: This notice announces that the Transportation Security Administration (TSA) has forwarded the Information Collection Request (ICR), Office of Management and Budget (OMB) control number 1652–0034, abstracted below to OMB for review and approval of an extension of the