

and Form FDA 3538 to facilitate the electronic submission of such information. We use the information collected with Form FDA 3538 to

register respondents to use the CVM ESS.  
*Description of Respondents:* The respondents are sponsors of new animal drug applications.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

21 CFR section	FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
11.2 .....	Form FDA 3538 .....	179	1.3	233	.08 (5 minutes) .....	19

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

We base our estimates on our experience with the submission of electronic information using the CVM ESS and the number of electronic registration or change requests received between January 1, 2018, and November 30, 2018. Our estimated burden for the information collection reflects an overall increase of 16 hours and a corresponding increase of 195 responses. We attribute this adjustment to the reauthorizations of both the Animal Drug User Fee Act and the Animal Generic Drug User Fee Act, which require sponsors to submit information electronically to the CVM's Office of New Animal Drug Evaluation. Because of this requirement, sponsors are now registering to use the CVM ESS in greater numbers than in previous years.

Dated: April 10, 2019.

**Lowell J. Schiller,**

*Acting Associate Commissioner for Policy.*

[FR Doc. 2019-07468 Filed 4-15-19; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket Nos. FDA-2011-N-0742; FDA-2018-N-1967; FDA-2018-N-2970; FDA-2017-N-1779; FDA-2008-N-0500; FDA-2012-N-0129; FDA-2009-D-0268; FDA-2014-D-0609; and FDA-2011-N-0776]

**Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White

Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, *PRAStaff@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:** The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at <https://www.reginfo.gov/public/do/PRAMain>. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution .....	0910-0045	12/31/2021
Biosimilar User Fee Program .....	0910-0718	12/31/2021
Surveys and Interviews with Investigational New Drug Sponsors to Assess Current Communication Practices with FDA Review Staff Under the Sixth Authorization of the Prescription Drug User Fee Act .....	0910-0863	12/31/2021
Disclosures of Descriptive Presentations in Professional Oncology Prescription Drug Promotion .....	0910-0864	12/31/2021
Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products .....	0910-0572	1/31/2022
General Licensing Provisions; Section 351(k) Biosimilar Applications .....	0910-0719	1/31/2022
Labeling of Certain Beers Subject to the Labeling Jurisdiction of the FDA .....	0910-0728	1/31/2022
Implementation of the Drug Supply Chain Security Act—Identification of Suspect Product and Notification .....	0910-0806	1/31/2022
Reclassification Petitions for Medical Devices .....	0910-0138	2/28/2022

Dated: April 10, 2019.

**Lowell J. Schiller,**

*Acting Associate Commissioner for Policy.*

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**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; RFA Panel: Tobacco Regulatory Biomedical Science—Basic.

*Date:* May 30, 2019.

*Time:* 10:00 a.m. to 5:30 p.m.

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* Joseph Thomas Peterson, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4118, MSC 7814, Bethesda, MD 20892, 301-408-9694, [petersonjt@csr.nih.gov](mailto:petersonjt@csr.nih.gov).

*Name of Committee:* Cardiovascular and Respiratory Sciences Integrated Review Group; Lung Cellular, Molecular, and Immunobiology Study Section.

*Date:* June 4–5, 2019.

*Time:* 8:00 a.m. to 3:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Radisson Hotel Baltimore Downtown, 101 West Fayette Street, Baltimore, MD 21201.

*Contact Person:* George M. Barnas, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2180, MSC 7818, Bethesda, MD 20892, 301-435-0696, [barnasg@csr.nih.gov](mailto:barnasg@csr.nih.gov).

*Name of Committee:* Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group; Imaging Guided Interventions and Surgery Study Section.

*Date:* June 4–5, 2019.

*Time:* 8:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Ileana Hancu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5116, Bethesda, MD 20817, 301-402-3911, [ileana.hancu@nih.gov](mailto:ileana.hancu@nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Early Phase Clinical Trials in Imaging and Image-Guided Interventions.

*Date:* June 5, 2019.

*Time:* 2:00 p.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Ileana Hancu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5116, Bethesda, MD 20817, 301-402-3911, [ileana.hancu@nih.gov](mailto:ileana.hancu@nih.gov).

*Name of Committee:* Risk, Prevention and Health Behavior Integrated Review Group;

Addiction Risks and Mechanisms Study Section.

*Date:* June 6–7, 2019.

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

*Agenda:* To review and evaluate grant applications.

*Place:* The Dupont Hotel, 1500 New Hampshire Avenue NW, Washington, DC 20036.

*Contact Person:* Kristen Prentice, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3112, MSC 7808, Bethesda, MD 20892, (301) 496-0726, [prenticekj@mail.nih.gov](mailto:prenticekj@mail.nih.gov).

*Name of Committee:* Risk, Prevention and Health Behavior Integrated Review Group; Behavioral Medicine, Interventions and Outcomes Study Section.

*Date:* June 10–11, 2019.

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

*Agenda:* To review and evaluate grant applications.

*Place:* The Fairmont Washington, DC, 2401 M Street NW, Washington, DC 20037.

*Contact Person:* Lee S. Mann, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3224, MSC 7808, Bethesda, MD 20892, 301-435-0677, [mannl@csr.nih.gov](mailto:mannl@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; PAR-18-018: Stimulating Innovations in Intervention Research for Cancer Prevention and Control.

*Date:* June 11, 2019.

*Time:* 10:30 a.m. to 1:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* The Fairmont Washington, DC, 2401 M Street NW, Washington, DC 20037.

*Contact Person:* Lee S. Mann, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3186, MSC 7848, Bethesda, MD 20892, 301-435-0677, [mannl@csr.nih.gov](mailto:mannl@csr.nih.gov).

(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 10, 2019.

**Ronald J. Livingston, Jr.,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

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**BILLING CODE 4140-01-P**

## DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS-2019-0018]

### Agency Information Collection Activities: REAL ID: Minimum Standards for Driver's Licenses and Identification Cards Acceptable by Federal Agencies for Office Purposes

**AGENCY:** Office of the Secretary, Department of Homeland Security.

**ACTION:** 60-Day notice and request for comments; extension without change of a currently approved collection, 1601-0005.

**SUMMARY:** The Department of Homeland Security (DHS), Office of the Secretary, will submit the following Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995.

**DATES:** Comments are encouraged and will be accepted until June 17, 2019. This process is conducted in accordance with 5 CFR 1320.1

**ADDRESSES:** You may submit comments, identified by docket number DHS-2019-0018, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Please follow the instructions for submitting comments.
- *Email:* [dhs.pra@hq.dhs.gov](mailto:dhs.pra@hq.dhs.gov). Please include docket number DHS-2019-0018 in the subject line of the message.

**SUPPLEMENTARY INFORMATION:** The REAL ID Act of 2005 (the Act) prohibits Federal agencies from accepting State-issued drivers' licenses or identification cards for any official purpose—defined by the Act and regulations as boarding commercial aircraft, accessing federal facilities, or entering nuclear power plants—unless the license or card is issued by a State that meets the requirements set forth in the Act. Title II of Division B of Public Law 109-13, codified at 49 U.S.C. 30301 note. The REAL ID regulations, which DHS issued in January 2008, establish the minimum standards that States must meet to comply with the Act. *See* 73 FR 5272, also 6 CFR part 37 (Jan. 29, 2008). These include requirements for presentation and verification of documents to establish identity and lawful status, standards for document issuance and security, and physical security requirements for driver's license production facilities. For a State to achieve full compliance, the Department of Homeland Security (DHS) must make a final determination that the State has met the requirements contained in the regulations and is compliant with the Act.<sup>1</sup> The regulations include new information reporting and record keeping requirements for States seeking a full compliance determination by DHS. As discussed in more detail below, States seeking DHS's full compliance determination must certify that they are meeting certain standards in the issuance of driver's licenses and