

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.*

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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

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**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,