

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

| Eye tracking study of DTC prescription drug advertisement viewing | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|-------------------------------------------------------------------|-----------------------|------------------------------------|------------------------|-----------------------------|-------------|
| Pilot study screener .....                                        | 200                   | 1                                  | 200                    | 0.03 (2 minutes) .....      | 6           |
| Main study screener .....                                         | 2,000                 | 1                                  | 2,000                  | 0.03 (2 minutes) .....      | 60          |
| Pilot study .....                                                 | 30                    | 1                                  | 30                     | 1 .....                     | 30          |
| Main study .....                                                  | 300                   | 1                                  | 300                    | 0.50 (30 minutes) ..        | 150         |
| Total .....                                                       |                       |                                    |                        |                             | 246         |

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

Dated: November 22, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2013-28599 Filed 11-27-13; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-N-0716]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Designated New Animal Drugs for Minor Use and Minor Species

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by December 30, 2013.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to [oira\\_submission@omb.eop.gov](mailto:oira_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0605. Also

include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., P150-400B, Rockville, MD 20850, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

#### Designated New Animal Drugs for Minor Use and Minor Species; 21 CFR Part 516—(OMB Control Number 0910-0605)—Extension

*Description:* The Minor Use and Minor Species Animal Health Act of 2004 (MUMS) (Pub. L. 108-282) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to authorize FDA to establish new regulatory procedures intended to make more medications legally available to veterinarians and animal owners for the treatment of minor animal species as well as uncommon diseases in major animal species. This legislation provides incentives designed to help pharmaceutical companies overcome the financial burdens they face in providing limited-demand animal drugs. These incentives are only available to sponsors whose drugs are “MUMS-designated” by FDA. Minor use drugs are drugs for use in major species (cattle, horses, swine, chickens, turkeys, dogs, and cats) that are needed for diseases that occur in only a small number of animals either because they occur infrequently or in limited geographic areas. Minor species are all

animals other than the major species; for example, zoo animals, ornamental fish, parrots, ferrets, and guinea pigs. Some animals of agricultural importance are also minor species. These include animals such as sheep, goats, catfish, and honeybees. Participation in the MUMS program is completely optional for drug sponsors so the associated paperwork only applies to those sponsors who request and are subsequently granted “MUMS designation.” The rule specifies the criteria and procedures for requesting MUMS designation as well as the annual reporting requirements for MUMS designees.

Section 516.20 (21 CFR 516.20) provides requirements on the content and format of a request for MUMS-drug designation; § 516.26 (21 CFR 516.26) provides requirements for amending MUMS-drug designation; provisions for change in sponsorship of MUMS-drug designation can be found under § 516.27 (21 CFR 516.27); under § 516.29 (21 CFR 516.29) are provisions for termination of MUMS-drug designation; under § 516.30 (21 CFR 516.30) are requirements for annual reports from sponsor(s) of MUMS-designated drugs; and under § 516.36 (21 CFR 516.36) are provisions for insufficient quantities of MUMS-designated drugs.

*Description of Respondents:* Pharmaceutical companies that sponsor new animal drugs.

In the **Federal Register** of July 2, 2013 (78 FR 39734), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

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| 21 CFR Section                                         | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|--------------------------------------------------------|-----------------------|------------------------------------|------------------------|-----------------------------|-------------|
| 516.20; Content and format of MUMS request .....       | 15                    | 5                                  | 75                     | 16                          | 1,200       |
| 516.26; Requirements for amending MUMS designation ... | 3                     | 1                                  | 3                      | 2                           | 6           |
| 516.27; Change in sponsorship .....                    | 1                     | 1                                  | 1                      | 1                           | 1           |

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

| 21 CFR Section                                | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours  |
|-----------------------------------------------|-----------------------|------------------------------------|------------------------|-----------------------------|--------------|
| 516.29; Termination of MUMS designation ..... | 2                     | 1                                  | 2                      | 1                           | 2            |
| 516.30; Requirements for annual reports ..... | 15                    | 5                                  | 75                     | 2                           | 150          |
| 516.36; Insufficient quantities .....         | 1                     | 1                                  | 1                      | 3                           | 3            |
| <b>Total</b> .....                            |                       |                                    |                        |                             | <b>1,362</b> |

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

The burden estimate for this reporting requirement was derived in our Office of Minor Use and Minor Species Animal Drug Development by extrapolating the current investigational new animal drug/new animal drug application reporting requirements for similar actions by this same segment of the regulated industry and from previous interactions with the minor use/minor species community.

Dated: November 22, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Submission for OMB Review; 30-Day Comment Request; Data Collection To Understand How NIH Programs Apply Methodologies To Improve Their Research Programs (MIRP)

**SUMMARY:** Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health, has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on September 9, 2013, page 55084 and allowed 60-days for public comment. One comment was received. However, the issues addressed in the comment were not related to the information collection proposed, and will not be considered in the finalization process. The purpose of this notice is to allow an additional 30 days for public comment. The National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1,

1995, unless it displays a currently valid OMB control number.

**Direct Comments to OMB:** Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA\_submission@omb.eop.gov* or by fax to 202-395-6974, Attention: NIH Desk Officer.

**DATES:** *Comment Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

**FOR FURTHER INFORMATION CONTACT:** To obtain a copy of the data collection plans and instruments, or request more information on the proposed project, contact: Ms. Dione Washington, Strategic Planning and Evaluation Branch, OSPIDA, NIAID, NIH, 6610 Rockledge Dr., Rm 2501, Bethesda, MD 20892-6620, or Email your request, including your address to *washingtondi@niaid.nih.gov*. Formal requests for additional plans and instruments must be requested in writing.

**Proposed Collection:** Data collection to understand how NIH programs apply methodologies to improve their research programs (MIRP), 0925-NEW, National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH).

**Need and Use of Information Collection:** In this submission, NIAID is requesting an OMB generic clearance for formative research activities relating to the collection of data to assist the Institute in understanding the usefulness of a range of methodologies that are employed to increase organizational effectiveness. The Office of Management and Budget (OMB) and Office of Science and Technology Policy (OSTP) have instructed agencies to apply rigorous strategy management principles to ensure resources are directed at high-priority programs and avoid duplication of effort. A key aspect to ensuring resources dedicated to these

programs are applied efficiently and effectively is to understand how NIH research programs apply methodologies to improve their organizational effectiveness. The degree of an organization's effectiveness is commonly recognized to be influenced by many factors. These can include the clarity of its purpose and strategy, how it allocates and structures its work, the processes used to carry out operations, the way technologies are used to support work, the people involved and their skills and abilities, the way relationships are managed with partners and stakeholders, and how leadership functions, particularly in terms of its ability to ensure that all the other components are aligned in supporting work towards the mission. Many methodologies are commonly employed in all sectors, including government, with the goal of increasing organizational effectiveness. Some examples of those used widely are strategic planning and strategy management, total quality management, change management, organizational assessment and intervention, organizational design, process improvement, leadership development, performance management, and workforce training and professional development, among others. There are many models and approaches to each of these methodologies. Each one can be implemented in a wide range of ways. Reflection on and learning from methodologies that have been used and the ways in which they have been employed is critical to continually ensuring that government functions effectively.

The primary use for information gathered through voluntary survey pilot testing, surveys, focus groups, interviews, and collaborative data interpretation meetings to understand the use of strategy management in research programs supported by the NIH. The information will improve approaches to implementing strategic management, which will lead to more efficient use of resources. Results gathered in these data will be used to