topics covered in the subject guidance document. The comments did not address the information collection elements solicited in our notice; however, we will consider the comments consistent with our good guidance practice regulations at 21 CFR 10.115.

Another comment covered multiple topics suggesting that FDA clarify more specifically the utility of the information being collected, and that some of the information collection may be duplicative. The comment also appears to question both FDA's role in and authority for the information collection, however, this comment goes beyond the scope of the topics solicited in our 60-day notice, and is therefore not discussed in this notice.

Another comment suggested that the burden estimate associated with new requests to be placed on the list was too low. We appreciate feedback regarding user experience with reporting information. Although we believe that the new module will ultimately reduce the time necessary for completing the application process, we have raised the estimate to 1 hour in deference to the comment.

Finally, other comments expressed encouragement for finding continued ways to improve the program, and we look forward to receiving continued feedback.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| Activity | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| New requests to be placed on the lists | 1,460 | 1 | 1,460 | [2] 0.5 | 730 |
| Third-party certification | 370 | 1 | 370 | 21 | 7,770 |
| Biennial update | 2,505 | 1 | 2,505 | [2] 0.5 | 1,253 |
| Third-party certification biennial update | 555 | 1 | 555 | 21 | 11,655 |
| Occasional updates | 300 | 1 | 300 | [2] 0.5 | 150 |
| Total | | | | | 21,558 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] (30 minutes).

The information collection reflects an increase in burden by 18,458 hours due to the consolidation of the information collections covered by OMB control numbers 0910–0839 and 0910–0320. Also, our current estimate of the number of foreign countries that may require us to establish lists in the next 3 years and the type of information they may require us to collect to maintain such lists has also resulted in an increase. At the same time, we have developed an electronic reporting portal that is expected to reduce the overall reporting time per submission. The portal will enhance the ability of firms to more efficiently request inclusion on export lists.

We base our estimate on the number of manufacturers/processors that have submitted new written requests, biennial updates, and occasional updates over the past 10 years. The estimate of the number of burden hours it will take a manufacturer/processor to gather the information needed to be placed on the list or update its information is based on our experience with manufacturers/processors submitting similar requests. We believe that the information to be submitted will be readily available to manufacturers/processors. This collection is incorporating additional information collected to maintain lists of eligible exporters of CFSAN-regulated products who wish to export to foreign markets, including the European Union, Chile and China under OMB control numbers 0910–0320, ''Request for Information from U.S. Processors that Export to the European Community'' and 0910–0839, ''Establishing and Maintaining Lists of U.S. Manufacturers/Processors with Interest in Exporting CFSAN-Regulated Products to China.''

We estimate that 1,460 firms will average 30 minutes (0.5 hour) to submit new requests for inclusion on the list, 2,505 firms will average 30 minutes (0.5 hour) to update their information every 2 years, and 300 firms will average 30 minutes (0.5 hour) to occasionally update their information in this system.

Some firms will need to provide documentation that they obtained third-party certification to certify that they have met the requirements of the importing country. Currently, only China has this requirement. Based on our experience with this program, 370 firms will spend about 21 hours to complete the third-party certification for a total of 7,770 burden hours. During the biennial update, we estimate that about half of the 1,110 manufacturers/processors for which the importing country requires third-party certification will be recertified, meaning that 555 manufacturers/processors (1,110 manufacturers/processors × 0.5) will get recertified each year. We estimate that it will take each such manufacturer/processor about 21 hours to complete the certification process for a total of 11,655 burden hours (555 manufacturers/processors × 21 hours).

We calculate, therefore, that the total burden for this collection is 21,558 hours.

Dated: June 6, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2019–12321 Filed 6–11–19; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2016–N–2474]**

### Agency Information Collection Activities; Proposed Collection; Comment Request; Reporting Associated With 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 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 the reporting associated with designation under the Minor Use and Minor Species Animal Health Act of 2004 (MUMS Act).

**DATES:** Submit either electronic or written comments on the collection of information by August 12, 2019.

**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 August 12, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 12, 2019. 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–2016–N–2474 for ''Reporting Associated With Designated New Animal Drugs for Minor Use and Minor Species.'' 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:** JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@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.

**Reporting Associated With Designated New Animal Drugs for Minor Use and Minor Species—21 CFR Part 516**

*OMB Control Number 0910–0605—Extension*

The MUMS Act (Pub. L. 108–282) amended the Federal Food, Drug, and Cosmetic 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 (*e.g.,* 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 (*e.g.,* 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 reporting only applies to those sponsors who request and are subsequently granted ''MUMS designation.''

Our regulations in 21 CFR part 516 specify the criteria and procedures for requesting MUMS designation as well as the annual reporting requirements for MUMS designees. Section 516.20 provides requirements on the content and format of a request for MUMS-drug designation; § 516.26 provides requirements for amending MUMS-drug designation; § 516.27 provides for change in sponsorship of MUMS-drug designation; § 516.29 provides for termination of MUMS-drug designation; § 516.30 contains the requirements for annual reports from sponsor(s) of MUMS-designated drugs; and § 516.36 sets forth consequences for insufficient quantities of MUMS-designated drugs.

*Description of Respondents:* The respondents to this information collection are pharmaceutical companies that sponsor new animal drugs.

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

TABLE 1—ESTIMATED ANNUAL REPORTING [1]

| 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 |
| 516.29; termination of MUMS designation | 2 | 1 | 2 | 1 | 2 |
| 516.30; requirements of annual reports | 15 | 5 | 75 | 2 | 150 |
| 516.36; insufficient quantities | 1 | 1 | 1 | 3 | 3 |
| Total | | | | | 1,362 |

[1] 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 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, and has not changed since the last OMB approval.

Dated: June 6, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2019–12316 Filed 6–11–19; 8:45 am]

**BILLING CODE 4164–01–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:* AIDS and Related Research Integrated Review Group, HIV Comorbidities and Clinical Studies Study Section.

*Date:* July 9–10, 2019.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Washington Marriott Georgetown, 1221 22nd Street NW, Washington, DC 20037.

*Contact Person:* Dimitrios Nikolaos Vatakis, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3190, Bethesda, MD 20892, 301–827–7480, *dimitrios.vatakis@nih.gov.*

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Fellowships: Physiology and Pathobiology of the Vascular and Hematological Systems.

*Date:* July 10, 2019.

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

*Agenda:* To review and evaluate grant applications.

*Place:* The William F. Bolger Center, 9600 Newbridge Drive, Potomac, MD 20854.

*Contact Person:* Katherine M. Malinda, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4140, MSC 7814, Bethesda, MD 20892, 301–435–0912, *Katherine_Malinda@csr.nih.gov.*

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, RFA–AI–18–054 U.S.-Brazil Collaborative Biomedical Research Program.

*Date:* July 10, 2019.

*Time:* 9:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* Jin Huang, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4095G, MSC 7812, Bethesda, MD 20892, 301–435–1230, *jh377p@nih.gov.*

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, PAR Panel: Clinical Pediatric and Fetal Applications.

*Date:* July 11, 2019.

*Time:* 10:00 a.m. to 5:00 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:* Khalid Masood, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5120, MSC 7854, Bethesda, MD 20892, 301–435–2392, *masoodk@csr.nih.gov.*

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, RFA–AI–