

<https://www.fda.gov/Drugs/NewsEvents/UCM559090.htm>. Registration requests for each meeting should be received during the time periods specified in table 1. FDA is limiting attendance due to restricted space. In addition, FDA may limit the number of participants from each organization based on space limitations. FDA recommends that each organization determine who should register for the public meeting to

represent his/her organization. This will help ensure that the meeting will have broad and varied representation, including across the pharmaceutical distribution supply chain. Registrants will receive confirmation of participation for their chosen meeting from FDA within 14 days of the date of each meeting. There is no registration fee for the public meetings. There will be no onsite registration. If registration

reaches maximum capacity, FDA will post a notice closing registration for the meeting on FDA's Web site at <https://www.fda.gov/Drugs/NewsEvents/UCM559090.htm>. If you need special accommodations due to a disability, please contact Daniel Bellingham (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the public meeting.

TABLE 1—PUBLIC MEETING INFORMATION

| Public meeting | Topics   | Date/Time  | Relevant section of this document or electronic address  |
|----------------|--|--|--|
| # 1 .....      | <ul style="list-style-type: none"> <li>Supply chain security in 2023 .....</li> <li>Enhanced drug distribution security needs.</li> </ul> Advance registration .....   | August 23, 2017, 9 a.m. to 4 p.m.<br><br>by July 31, 2017 .....      | Online registration only at <a href="https://www.fda.gov/Drugs/NewsEvents/UCM559090.htm">https://www.fda.gov/Drugs/NewsEvents/UCM559090.htm</a> . No onsite registration.<br>See "Comments".<br>See <b>FOR FURTHER INFORMATION CONTACT</b> . |
|                | Comment period closes .....  | September 22, 2017 .....   |  |
| # 2 .....      | <ul style="list-style-type: none"> <li>Electronic interoperability .....</li> <li>Standards for data exchange .....</li> <li>Data architecture .....</li> <li>Aggregation and inference.</li> </ul> Advance registration ..... | December 5–6, 2017, 9 a.m. to 4 p.m.<br><br>October 2–27, 2017 ..... | Online registration only at <a href="https://www.fda.gov/Drugs/NewsEvents/UCM559090.htm">https://www.fda.gov/Drugs/NewsEvents/UCM559090.htm</a> . No onsite registration.<br>See "Comments".<br>See <b>FOR FURTHER INFORMATION CONTACT</b> . |
|                | Comment period closes .....  | January 5, 2018 .....  |  |
| # 3 .....      | <ul style="list-style-type: none"> <li>Further refinement of enhanced drug distribution security needs.</li> <li>Building capacity for a unit-level system.</li> </ul> Advance registration .....                              | February 28, 2018, 9 a.m. to 4 p.m.<br><br>January 2–26, 2018 .....  | Online registration only at <a href="https://www.fda.gov/Drugs/NewsEvents/UCM559090.htm">https://www.fda.gov/Drugs/NewsEvents/UCM559090.htm</a> . No onsite registration.<br>See "Comments".<br>See <b>FOR FURTHER INFORMATION CONTACT</b> . |
|                | Comment period closes .....  | March 30, 2018 .....   |  |

**IV. Webcasting of the Public Meeting**

Portions of each public meeting will be recorded and webcast on the day of the meeting. Information for how to access the webcast will be available at <https://www.fda.gov/Drugs/NewsEvents/UCM559090.htm> within 7 days prior to each public meeting. The webcast will be conducted in listening mode only.

Dated: July 14, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

[FR Doc. 2017–15204 Filed 7–19–17; 8:45 am]

**BILLING CODE 4164–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2010–N–0597]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Index of Legally Marketed Unapproved New Animal Drugs for 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 August 21, 2017.

**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 0910–0620. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Ila S. Mizrahi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726.

**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. Index of Legally Marketed Unapproved New Animal Drugs for Minor Species—21 CFR part 516 OMB Control Number 0910-0620—Extension

The Minor Use and Minor Species Animal Health Act of 2004 (the MUMS Act) (Pub. L. 108-282) added section 572 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360ccc-1), which authorizes 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 (species other than cattle, horses, swine, chickens, turkeys, dogs, and cats). In enacting the MUMS Act, Congress sought to encourage the development of these

new animal drugs. Congress recognized that the markets for drugs intended to treat these species, diseases, or conditions are so small that there are often insufficient economic incentives to motivate drug companies to develop data to support approvals. Further, Congress recognized that some minor species populations are too small or their management systems too diverse to make it practical to conduct traditional studies to demonstrate safety and effectiveness of animal drugs for such uses. As a result of these limitations, drug companies have generally not been willing or able to collect data to support legal marketing of drugs for these species, diseases, or conditions. Consequently, Congress enacted the MUMS Act to provide incentives to develop new animal drugs for minor species, while still ensuring appropriate safeguards for animal and human health. Section 572 of the FD&C Act provides for a public index listing of legally marketed unapproved new animal drugs for minor species. FDA regulations in part 516 (21 CFR part 516) specify, among other things, the criteria and procedures for requesting eligibility for indexing and for

requesting addition to the index, as well as the annual reporting requirements for index holders. The administrative procedures and criteria for indexing a new animal drug for use in a minor species are set forth in 21 CFR 516.111 through 516.171. Section 516.165 sets forth the annual reporting requirements for index holders. FDA needs the information to determine: (1) The eligibility of a new animal drug for indexing; (2) that a qualified expert panel proposed to review certain information regarding the new animal drug meets the selection criteria listed in the regulations; (3) whether the Agency agrees with the recommendation of a qualified expert panel that a drug be added to the index; and (4) whether there may be grounds for removing a drug from the index.

In the **Federal Register** of December 21, 2016 (81 FR 93689), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment, which was outside the scope of the comment requests in the notice.

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

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

| 21 CFR section   | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|--|-----------------------|------------------------------------|------------------------|-----------------------------|-------------|
| 516.119—requires a foreign drug company to submit and update the name and address of a permanent U.S. resident agent .....               | 2                     | 1                                  | 2                      | 1                           | 2           |
| 516.121—written request for a meeting with FDA to discuss the requirements for indexing a new animal drug .....                          | 30                    | 2                                  | 60                     | 4                           | 240         |
| 516.123—written request for an informal conference and a requestor's written response to an FDA initial decision denying a request ..... | 3                     | 1                                  | 3                      | 8                           | 24          |
| 516.125—correspondence and information associated with investigational use of new animal drugs intended for indexing .....               | 2                     | 3                                  | 6                      | 20                          | 120         |
| 516.129—content and format of a request for determination of eligibility for indexing .....  | 30                    | 2                                  | 60                     | 20                          | 1,200       |
| 516.141—information to be submitted to FDA by a requestor seeking to establish a qualified expert panel .....                            | 20                    | 1                                  | 20                     | 16                          | 320         |
| 516.143—content and format of the written report of the qualified expert panel .....   | 20                    | 1                                  | 20                     | 120                         | 2,400       |
| 516.145—content and format of a request for addition to the Index .....  | 20                    | 1                                  | 20                     | 20                          | 400         |
| 516.161—content and format of a request for modification of an indexed drug .....  | 1                     | 1                                  | 1                      | 4                           | 4           |
| 516.163—information to be contained in a request to FDA to transfer ownership of a drug's index file to another person .....             | 1                     | 1                                  | 1                      | 2                           | 2           |
| 516.165—requires drug experience reports and distributor statements to be submitted to FDA .....   | 10                    | 2                                  | 20                     | 8                           | 160         |
| Total .....  |                       |                                    |                        |                             | 4,872       |

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>

| 21 CFR Section   | Number of record-keepers | Number of records per recordkeeper | Total annual records | Average burden per recordkeeping | Total hours |
|--|--------------------------|------------------------------------|----------------------|----------------------------------|-------------|
| 516.141—requires the qualified expert panel leader to maintain a copy of the written report and all notes or minutes relating to panel deliberations that are submitted to the requestor for 2 years after the report is submitted ..... | 30                       | 2                                  | 60                   | *.5                              | 30          |
| 516.165—requires the holder of an indexed drug to maintain records of all information pertinent to the safety or effectiveness of the indexed drug, from foreign and domestic sources .....  | 10                       | 2                                  | 20                   | 1                                | 20          |
| Total .....  |                          |                                    |                      |                                  | 50          |

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.  
\*30 minutes.

We based our estimates in tables 1 and 2 on our experience with the MUMS indexing program and the requests for eligibility for indexing and for addition to the index, as well as the periodic drug experience reports submitted during the past 3 years. The burden has not changed since the last OMB approval.

Dated: July 13, 2017.

**Anna K. Abram,**  
*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

[FR Doc. 2017–15206 Filed 7–19–17; 8:45 am]

**BILLING CODE 4164-01-P**

**DEPARTMENT OF HOMELAND SECURITY**

**Federal Emergency Management Agency**

[Docket ID FEMA–2017–0002; Internal Agency Docket No. FEMA–B–1724]

**Proposed Flood Hazard Determinations**

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Notice.

**SUMMARY:** Comments are requested on proposed flood hazard determinations, which may include additions or modifications of any Base Flood Elevation (BFE), base flood depth, Special Flood Hazard Area (SFHA) boundary or zone designation, or regulatory floodway on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports for the communities listed in the table below. The purpose of this notice is to seek general information and comment regarding the preliminary FIRM, and where applicable, the FIS report that the Federal Emergency Management Agency

(FEMA) has provided to the affected communities. The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect for participation in the National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report, once effective, will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings.

**DATES:** Comments are to be submitted on or before October 18, 2017.

**ADDRESSES:** The Preliminary FIRM, and where applicable, the FIS report for each community are available for inspection at both the online location and the respective Community Map Repository address listed in the tables below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at [www.msc.fema.gov](http://www.msc.fema.gov) for comparison.

You may submit comments, identified by Docket No. FEMA–B–1724, to Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW., Washington, DC 20472, (202) 646–7659, or (email) [patrick.sacbibit@fema.dhs.gov](mailto:patrick.sacbibit@fema.dhs.gov).

**FOR FURTHER INFORMATION CONTACT:** Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW., Washington, DC 20472, (202) 646–7659, or (email) [patrick.sacbibit@fema.dhs.gov](mailto:patrick.sacbibit@fema.dhs.gov); or visit the FEMA Map Information eXchange (FMIX) online at [www.floodmaps.fema.gov/fhm/fmx\\_main.html](http://www.floodmaps.fema.gov/fhm/fmx_main.html).

**SUPPLEMENTARY INFORMATION:** FEMA proposes to make flood hazard determinations for each community listed below, in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. These flood hazard determinations are used to meet the floodplain management requirements of the NFIP and also are used to calculate the appropriate flood insurance premium rates for new buildings built after the FIRM and FIS report become effective.

The communities affected by the flood hazard determinations are provided in the tables below. Any request for reconsideration of the revised flood hazard information shown on the Preliminary FIRM and FIS report that satisfies the data requirements outlined in 44 CFR 67.6(b) is considered an appeal. Comments unrelated to the flood hazard determinations also will be considered before the FIRM and FIS report become effective.

Use of a Scientific Resolution Panel (SRP) is available to communities in support of the appeal resolution process. SRPs are independent panels of experts in hydrology, hydraulics, and other pertinent sciences established to review conflicting scientific and technical data and provide recommendations for resolution. Use of the SRP only may be exercised after