

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

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
740(d)(1)(A); significant barrier to innovation.	55	1 time for each application	55	2 .....	110
740(d)(1)(B); fees exceed cost .....	8	3.75 .....	30	0.5 (30 minutes) ....	15
740(d)(1)(C); free choice feeds .....	5	1 time for each application	5	2 .....	10
740(d)(1)(D); minor use or minor species	69	1 time for each application	69	2 .....	138
740(d)(1)(E); small business .....	1	1 time for each application	1	2 .....	2
Request for reconsideration of a decision	1	1 time for each application	1	2 .....	2
Request for review (user fee appeal officer).	0	1 time for each application	0	0 .....	0
<b>Total</b> .....					<b>277</b>

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

Based on FDA’s database system, from fiscal year (FY) 2014 to 2016 there were an estimated 177 sponsors subject to ADUFA. However, not all sponsors will have any submissions in a given year and some may have multiple submissions. The total number of waiver requests is based on the average number of submission types received by FDA in FY 2014 to 2016.

Dated: October 12, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2010–N–0601]

**Agency Information Collection Activities; Proposed Collection; Comment Request; Current Good Manufacturing Practice Regulations for Medicated Feeds**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the 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 recordkeeping requirements for manufacturers of medicated animal feeds.

**DATES:** Submit either electronic or written comments on the collection of information by December 16, 2016.

**ADDRESSES:** You may submit comments as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://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 <http://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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, 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–2010–N–0601 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Current Good Manufacturing Practice Regulations for Medicated Feeds.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management 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 <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. 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: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@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.

**Current Good Manufacturing Practice Regulations for Medicated Feeds—21 CFR Part 225**

*OMB Control Number 0910–0152—Extension*

Under section 501 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 351), FDA has the statutory authority to issue current good manufacturing practice (cGMP) regulations for drugs, including medicated feeds. Medicated feeds are administered to animals for the prevention, cure, mitigation, or treatment of disease, or growth promotion and feed efficiency. Statutory requirements for cGMPs have been codified under part 225 (21 CFR part 225). Medicated feeds that are not manufactured in accordance with these regulations are considered adulterated under section 501(a)(2)(B) of the FD&C Act. Under part 225, a manufacturer is required to establish, maintain, and retain records for a medicated feed,

including records to document procedures required during the manufacturing process to assure that proper quality control is maintained. Such records would, for example, contain information concerning receipt and inventory of drug components, batch production, laboratory assay results (*i.e.* batch and stability testing), labels, and product distribution.

This information is needed so that FDA can monitor drug usage and possible misformulation of medicated feeds to investigate violative drug residues in products from treated animals and to investigate product defects when a drug is recalled. In addition, FDA will use the cGMP criteria in part 225 to determine whether or not the systems and procedures used by manufacturers of medicated feeds are adequate to assure that their feeds meet the requirements of the FD&C Act as to safety, and also that they meet their claimed identity, strength, quality, and purity, as required by section 501(a)(2)(B) of the FD&C Act.

A license is required when the manufacturer of a medicated feed involves the use of a drug or drugs that FDA has determined requires more control because of the need for a withdrawal period before slaughter or because of carcinogenic concerns. Conversely, a license is not required and the recordkeeping requirements are less demanding for those medicated feeds for which FDA has determined that the drugs used in their manufacture need less control. Respondents to this collection of information are commercial feed mills and mixer-feeders.

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

**TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN**  
[Registered licensed commercial feed mills]<sup>1</sup>

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeper	Total hours
225.42(b)(5) through (b)(8) .....	877	260	228,020	1 .....	228,020
225.28(c) and (d) .....	877	45	39,465	0.50 (30 minutes) ..	19,732.5
225.80(b)(2) .....	877	1,600	1,403,200	0.12 (7 minutes) ....	168,384
225.102(b)(1) .....	877	7,800	6,840,600	0.08 (5 minutes) ....	547,248
225.110(b)(1) and (b)(2) .....	877	7,800	6,840,600	0.02 (1 minute) .....	136,812
225.115(b)(1) and (b)(2) .....	877	5	4,385	0.12 (7 minutes) ....	526.2
<b>Total</b> .....	.....	.....	.....	.....	<b>1,100,722.7</b>

<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  
[Registered licensed mixer-feeders] <sup>1</sup>

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeper	Total hours
225.42(b) through (b)(8) .....	100	260	26,000	0.15 (9 minutes) ....	3,900
225.58(c) through (d) .....	100	36	3,600	0.50 (30 minutes) ..	1,800
225.80(b) (2) .....	100	48	4,800	0.12 (7 minutes) ....	576
225.102(b)(1) through (b)(5) .....	100	260	26,000	0.40 (24 minutes) ..	10,400
Total .....					16,676

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

TABLE 3—ESTIMATED ANNUAL RECORDKEEPING BURDEN  
[Nonregistered unlicensed commercial feed mills] <sup>1</sup>

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeper	Total hours
225.142 .....	4,186	4	16,744	1 .....	16,744
225.158 .....	4,186	1	4,186	4 .....	16,744
225.180 .....	4,186	96	401,856	0.12 (7 minutes) ....	48,223
225.202 .....	4,186	260	1,088,360	0.65 (39 minutes) ..	707,434
Total .....					789,145

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

TABLE 4—ESTIMATED ANNUAL RECORDKEEPING BURDEN  
[Nonregistered unlicensed mixer-feeders] <sup>1</sup>

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeper	Total hours
225.142 .....	3,400	4	13,600	1 .....	13,600
225.158 .....	3,400	1	3,400	4 .....	13,600
225.180 .....	3,400	32	108,800	0.12 (7 minutes) ....	13,056
225.202 .....	3,400	260	884,000	0.33 (20 minutes) ..	291,720
Total .....					331,976

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

The estimate of time required for record preparation and maintenance is based on Agency communications with industry. Other information needed to finally calculate the total burden hours (*i.e.*, number of recordkeepers, number of medicated feeds being manufactured, etc.) is derived from Agency records and experience.

Dated: October 12, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2016-N-0001]

**Substitutability of Generic Drugs: Perceptions and Reality; Public Workshop**

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

**ACTION:** Notice of public workshop.

**SUMMARY:** The Food and Drug Administration (FDA), in collaboration with the Johns Hopkins University Center of Excellence in Regulatory Science and Innovation, is announcing a public workshop entitled “Substitutability of Generic Drugs: Perceptions and Reality.” The objective of this workshop is to discuss FDA and industry practices related to postmarket surveillance of generic drugs,

postmarket generic drug research activities, public perceptions of generic drug quality and effectiveness, and verification of therapeutic equivalence of generic drugs. This workshop will also give stakeholders, including scientists from government, academia, and industry, patient advocacy groups, clinicians, pharmacists, and the general public an opportunity to provide their insights on future research needs in postmarket surveillance of generic drugs.

**DATES:** The public workshop will be held on November 18, 2016, from 8:30 a.m. to 4:30 p.m.

**ADDRESSES:** The public workshop will be held at FDA’s White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine