TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR HUMAN DRUGS [1]

E6(R2) Good clinical practice; International Council for Harmonisation; guidance for industry	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Section 5.0—Quality Management (including sections 5.0.1 to 5.0.7)—Developing a Quality Management System	1,457	1	1,457	60	87,420

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN FOR HUMAN DRUGS [1]

E6(R2) Good clinical practice; International Council for Harmonisation; guidance for industry	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Section 5.0.7—Risk Reporting—Describing the Quality Management Approach Implemented in a Clinical Trial and Summarizing Important Deviations From the Predefined Quality Tolerance Limits and Remedial Actions Taken in the Clinical Study Report	1,457	4.6	6,702	3	20,107

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 3—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR BIOLOGICS [1]

E6(R2) Good clinical practice; International Council for Harmonisation; guidance for industry	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Section 5.0—Quality Management (including 5.0.1 to 5.0.7)—Developing a Quality Management System	218	1	218	60	13,080

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 4—ESTIMATED ANNUAL REPORTING BURDEN FOR BIOLOGICS [1]

E6(R2) Good clinical practice; International Council for Harmonisation; guidance for industry	Number of responses	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Section 5.0.7—Risk Reporting—Describing the Quality Management Approach Implemented in a Clinical Trial and Summarizing Important Deviations From the Predefined Quality Tolerance Limits and Remedial Actions Taken in the Clinical Study Report	218	3.69	804	3	2,413

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: July 12, 2017.

Anna K. Abram,

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

[FR Doc. 2017–14999 Filed 7–17–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0601]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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 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 17, 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.* All comments should be identified with the OMB control number 0910–0152. Also include the FDA docket number found in brackets in the heading of this document.

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

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.

In the **Federal Register** of October 17, 2016 (81 FR 71508), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one letter in response to the notice, which contained multiple comments. One comment was generally supportive of the recordkeeping provisions of part 225. Another comment suggested that we should collect data from manufacturers of medicated feed, and described several benefits of having this information. Our regulations in part 225 require recordkeeping to document procedures required during the manufacturing process to assure that proper quality control is maintained. The regulations do not require manufacturers to submit this information to us on a routine basis but, rather, to make the information available to us upon inspection. To the extent that the comments recommend changes to our cGMP regulations for medicated feed, which can only be accomplished by rulemaking, the comments were outside the scope of the four collection of information topics on which the notice requested comments and will not be discussed in this document.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN

[Registered Licensed Commercial Feed Mills] [1]

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
225.42(b)(5) through (b)(8), requires records of receipt, storage, and inventory control of medicated feeds.	877	260	228,020	1	228,020
225.58(c) and (d), requires records of the results of periodic assays for medicated feeds that are in accord with label specifications and also those medicated feeds not within documented permissible assay limits.	877	45	39,465	.50 (30 minutes)	19,732.5
225.80(b)(2), requires that verified medicated feed label(s) be kept for 1 year.	877	1,600	1,403,200	.12 (7 minutes)	168,384
225.102(b)(1), requires records of Master Record Files and production records for medicated feeds.	877	7,800	6,840,600	.08 (5 minutes)	547,248
225.110(b)(1) and (b)(2), requires maintenance of distribution records for medicated feeds.	877	7,800	6,840,600	.02 (1 minute)	136,812
225.115(b)(1) and (b)(2), requires maintenance of complaint files by the medicated feed manufacturer.	877	5	4,385	.12 (7 minutes)	526.2
Total					1,100,722.7

[1] 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] [1]

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
225.42(b)(5) through (b)(8), requires records of receipt, storage, and inventory control of medicated feeds.	100	260	26,000	.15 (9 minutes)	3,900
225.58(c) and (d), requires records of the results of periodic assays for medicated feeds that are in accord with label specifications and also those medicated feeds not within documented permissible assay limits.	100	36	3,600	.50 (30 minutes)	1,800
225.80(b)(2), requires that verified medicated feed label(s) be kept for 1 year.	100	48	4,800	.12 (7 minutes)	576
225.102(b)(1) through (b)(5), requires records of Master Record Files and production records for medicated feeds.	100	260	26,000	.40 (24 minutes)	10,400
Total	.....	.....	.....	.....	16,676

[1] 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] [1]

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
225.142, requires procedures for identification, storage, and inventory control (receipt and use) of Type A medicated articles and Type B medicated feeds.	4,186	4	16,744	1	16,744
225.158, requires records of investigation and corrective action when the results of laboratory assays of drug components indicate that the medicated feed is not in accord with the permissible assay limits.	4,186	1	4,186	4	16,744
225.180, requires identification, storage, and inventory control of labeling in a manner that prevents label mix-ups and assures that correct labels are used for medicated feeds.	4,186	96	401,856	.12 (7 minutes)	48,223
225.202, requires records of formulation, production, and distribution of medicated feeds.	4,186	260	1,088,360	.65 (39 minutes)	707,434
Total	.....	.....	.....	.....	789,145

[1] 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] [1]

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
225.142, requires procedures for identification, storage, and inventory control (receipt and use) of Type A medicated articles and Type B medicated feeds.	3,400	4	13,600	1	13,600
225.158, requires records of investigation and corrective action when the results of laboratory assays of drug components indicate that the medicated feed is not in accord with the permissible assay limits.	3,400	1	3,400	4	13,600
225.180, requires identification, storage, and inventory control of labeling in a manner that prevents label mix-ups and assures that correct labels are used for medicated feeds.	3,400	32	108,800	.12 (7 minutes)	13,056
225.202, requires records of formulation, production, and distribution of medicated feeds.	3,400	260	884,000	.33 (20 minutes)	291,720

TABLE 4—ESTIMATED ANNUAL RECORDKEEPING BURDEN—Continued

[Nonregistered Unlicensed Mixer-Feeders] [1]

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Total	.....	.....	.....	.....	331,976

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We based our estimate of the time required for record preparation and maintenance on our communications with industry. We derived additional information needed to calculate the total burden hours (*i.e.,* number of recordkeepers, number of medicated feeds being manufactured, etc.) from our records and experience. The burden has not changed since the last OMB approval.

Dated: July 12, 2017.

Anna K. Abram,

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

[FR Doc. 2017–14995 Filed 7–17–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2017–0692]

Equivalency Determination for ''Marine Charts,'' ''Charts,'' or ''Maps,'' ''Publications,'' and Navigation Functions—Notice of Availability of Navigation and Vessel Inspection Circular 01–16 Change 1

AGENCY: Coast Guard, DHS.

ACTION: Notice of availability.

SUMMARY: The Coast Guard (USCG) is announcing, the availability of Navigation and Vessel Inspection Circular (NVIC) 01–16 change 1. The NVIC provides that display of certain electronic charts and publications will meet—as an equivalency—the ''marine charts,'' ''charts,'' ''maps,'' or ''publications'' carriage requirements and provides for an equivalency for position fixing and plotting. USCG intends, by this policy, to provide a path for U.S. flagged vessels to replace paper charts and most hard copy publications if so desired.

FOR FURTHER INFORMATION CONTACT: Please address questions or feedback concerning this policy to LCDR Matthew Walter, telephone 202–372–1565 or email *cgnav@uscg.mil.*

SUPPLEMENTARY INFORMATION: In response to recommendations from Coast Guard Federal Safety Advisory Committees, industry stakeholders and agency partners, the Coast Guard updated its original policy on electronic charts and publications. Navigation and Vessel Inspection Circular (NVIC) 01–16 change 1 is revised to focus on the equivalency determination for charts, publications and, newly added, navigation functions. It only accepts certain electronic charts as described. It requires vessels that operate offshore to display charts on certain systems. It describes the minimum performance requirements for equipment receiving position information and restates our policy on electronic navigation publications.

Title 33 of the Code of Federal Regulations requires ''currently corrected marine charts'' of a large enough scale and with enough detail to make safe navigation possible. In 2002, the Coast Guard authorized U.S. flagged SOLAS-compliant vessels to use an Electronic Chart Display and Information System (ECDIS) in lieu of paper charts.[1] That policy did not apply to the U.S. flagged vessels engaged solely on domestic voyages. Therefore, the Coast Guard is publishing an equivalency to address electronic chart carriage on those vessels.

Title 33 of the CFR 164 also requires that some vessels fix their position [2] and other vessels fix and plot their position.[3] The USCG recognizes the benefit of real-time positioning data, and that it can provide greater situational awareness than what could be achieved using paper charts. Therefore, USCG is announcing an equivalency to fixing and plotting. Title 33 of the CFR, along with the International Convention of Safety of Life at Sea (SOLAS) Chapter V Regulation 27, also requires currently corrected editions of, or applicable currently corrected extracts from, nautical publications necessary for the intended voyage. In 2010, USCG announced policy accepting some electronic publications in lieu of paper publications.[4] NVIC 01–16 change 1 does not substantively change this USCG publication policy, but rather consolidates information.

Additionally, NVIC 01–16 change 1 also provides guidance to marine inspectors regarding how to identify approved and/or appropriate electronic charts, display systems, position information and electronic publications. Finally, this Circular recommends practices that vessel owners and operators should consider when navigating with the assistance of electronics.

This Circular is not a substitute for applicable legal requirements, nor is it itself a rule. It does not provide equivalence for the purposes of SOLAS certificates. Mariners are responsible to safely navigate and follow applicable regulatory requirements.

Dated: July 10, 2017.

RADM Paul F. Thomas,

Assistant Commandant for Prevention Policy, U.S. Coast Guard.

[FR Doc. 2017–15056 Filed 7–17–17; 8:45 am]

BILLING CODE 9110–04–P

[1] 67 **Federal Register** 53382 as amended by 69 **Federal Register** 42192, Carriage of Navigation Equipment for Ships on International Voyages.

[2] 33 CFR 164.11 & 164.78—Self-propelled vessels 1600 or more gross tons and towing vessels 12 meters or more in length.

[3] 33 CFR 164.11—Self-propelled vessels 1600 or more gross tons.

[4] CG–543 Policy Letter 10–05 canceled and replaced by Navigation and Vessel Inspection Circular 01–16.

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4320–DR; Docket ID FEMA–2017–0001]

Tennessee; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Tennessee (FEMA–4320–DR), dated June 23, 2017, and related determinations.

DATES: *Effective Date:* June 23, 2017.