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 recordkeeper	Total hours
Total					331,976

[1] 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: June 17, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–14472 Filed 6–19–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–N–0389]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Current Good Manufacturing Practice Regulations for Type A Medicated Articles

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 July 21, 2014.

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 0910–0154. 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, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *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 Type A Medicated Articles—21 CFR Part 226 (OMB Control Number 0910–0154)—Extension

Under section 501 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), FDA has the statutory authority to issue current good manufacturing practice (cGMP) regulations for drugs, including Type A medicated articles. A Type A medicated article is a feed product containing a concentrated drug diluted with a feed carrier substance. A Type A medicated article is intended solely for use in the manufacture of another Type A medicated article or a Type B or Type C medicated feed. Medicated feeds are administered to animals for the prevention, cure, mitigation, or treatment of disease or for growth promotion and feed efficiency.

Statutory requirements for cGMPs for Type A medicated articles have been codified in part 226 (21 CFR part 226). Type A medicated articles which are not manufactured in accordance with these regulations are considered adulterated under section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)(B). Under part 226, a manufacturer is required to establish, maintain, and retain records for Type A medicated articles, including records to document procedures required under 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) and product distribution.

This information is needed so that FDA can monitor drug usage and possible misformulation of Type A medicated articles. The information could also prove useful to FDA in investigating product defects when a drug is recalled. In addition, FDA will use the cGMP criteria in part 226 to determine whether or not the systems used by manufacturers of Type A medicated articles are adequate to assure that their medicated articles meet the requirements of the FD&C Act as to safety and also meet the article's claimed identity, strength, quality, and purity, as required by section 501(a)(2)(B) of the FD&C Act. The respondents for Type A medicated articles are pharmaceutical firms that manufacture both human and veterinary drugs, those firms that produce only veterinary drugs, and commercial feed mills.

In the **Federal Register** of April 7, 2014 (79 FR 19093), 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:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeper	Total hours
226.42	65	260	16,900	0.75 (45 minutes)	12,675
226.58	65	260	16,900	1.75	29,575
226.80	65	260	16,900	0.75 (45 minutes)	12,675

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]—Continued

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeper	Total hours
226.102	65	260	16,900	1.75	29,575
226.110	65	260	16,900	0.25 (15 minutes)	4,225
226.115	65	10	650	0.5 (30 minutes)	325
Total					89,050

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

The estimate of time required for record preparation and maintenance is based on previous Agency communications with industry. Other information needed to calculate the total burden hours (i.e., manufacturing sites, number of Type A medicated articles being manufactured, etc.) are derived from Agency records and experience.

Dated: June 16, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–14471 Filed 6–19–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0663]

Draft Guidance for Industry: Determining the Need for and Content of Environmental Assessments for Gene Therapies, Vectored Vaccines, and Related Recombinant Viral or Microbial Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for Industry: Determining the Need for and Content of Environmental Assessments for Gene Therapies, Vectored Vaccines, and Related Recombinant Viral or Microbial Products'' dated June 2014. The draft guidance document provides investigational new drug application (IND) sponsors and applicants for a biologics license application (BLA), or a supplement to a BLA, with recommendations on considerations when assessing whether to submit an Environmental Assessment (EA) for gene therapies, vectored vaccines, and related recombinant viral or microbial products (GTVVs). The guidance also contains recommendations as to what information should be included in an EA and what sponsors and applicants can expect once an EA is filed. The guidance, when finalized, will supplement the guidance entitled ''Guidance for Industry: Environmental Assessment of Human Drug and Biologics Applications,'' dated July 1998 (1998 Guidance) and will also supersede those recommendations for GTVVs in section IV.B.1 Assessing Toxicity to Environmental Organisms'' of the guidance.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by September 18, 2014.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–7800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Tami Belouin, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Guidance for Industry: Determining the Need for and Content of Environmental Assessments for Gene Therapies, Vectored Vaccines, and Related Recombinant Viral or Microbial Products'' dated June 2014. The draft guidance document provides IND sponsors and applicants for a BLA, or a supplement to a BLA, with recommendations on considerations when assessing whether to submit an EA for GTVVs. The guidance also contains recommendations as to what information should be included in an EA and what sponsors and applicants can expect once an EA is filed. Products addressed in the guidance include all GTVVs, but not live-attenuated viral or microbial vaccines created by traditional methods such as serial passaging or recombinant protein-based vaccines. The guidance, when finalized, will supplement the 1998 Guidance, and will also supersede those recommendations for GTVVs in section IV.B.1 entitled ''Assessing Toxicity to Environmental Organisms'' of the guidance.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 25 have been approved under OMB control number 0910–0322; the collections of