Seleda Perryman,
Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0511]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medicated Feed Mill License Application

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 a collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on the medicated feed mill licensing applications.

DATES: Submit written or electronic comments on the collection of information by December 28, 2009.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3793.

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.

Medicated Feed Mill License Application—21 CFR Part 515 (OMB Control Number 0910–0337)—Extension

The Animal Drug Availability Act (ADAA) of October 9, 1996, amended section 512 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b) to replace the system for the approval of specific medicated feed with a general licensing system for feed mills. Before passage of the ADAA, medicated feed manufacturers were required to obtain approval of Medicated Feed Applications (MFAs), in order to manufacture certain types of medicated feeds. An individual approved MFA was required for each and every applicable medicated feed. The ADAA streamlined the paperwork process for gaining approval to manufacture medicated feeds by replacing the MFA system with a facility license for each medicated feed manufacturing facility.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
515.10(b)	20	1	20	0.25	5
515.11(b)	75	1	75	0.25	18.75
515.23	40	1	40	0.25	10
515.30(c)	0.15	1	0.15	24	3.6
Total Burden Hours					37.35

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
510.305	1,070	1	1,070	0.03	32.10

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

The estimated annual reporting burden on industry is 37.35 hours as shown in table 1 of this document. Industry estimates it takes about 1/4 hour to submit the application. We estimate 135 original and supplemental applications, and voluntary revocations for a total of 33.75 hours (135 submissions x 1/4 hour). An additional 3.6 hours is added for the rare notice of opportunity for a hearing to not approve or revoke an application. Finally, we estimate 30 hours for maintaining and retrieving labels as required by 21 CFR 510.305 and shown in table 2 of this document. We estimated 0.03 hours for each of the approximately 1,000 licensees. Thus, the total annual burden for reporting and recordkeeping requirements is estimated to be 67.35 hours.

Dated: October 20, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–25915 Filed 10–27–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0215]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Recordkeeping Requirements for Microbiological Testing and Corrective Measures for Bottled Water

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 November 27, 2009.

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: 202–395–6974, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–NEW and title ''Recordkeeping Requirements for Microbiological Testing and Corrective Measures for Bottled Water.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3794, e-mail: *JonnaLynn.Capezzuto@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.

Recordkeeping Requirements for Microbiological Testing and Corrective Measures for Bottled Water—21 CFR 129.35(a)(3)(i) and 129.80(g) and (h)

FDA has amended its bottled water regulations in parts 129 and 165 (21 CFR parts 129 and 165) by requiring that if any coliform organisms are detected in weekly total coliform testing of finished bottled water, followup testing must be conducted to determine whether any of the coliform organisms are *E. coli*. FDA also amended the adulteration provision of the bottled water standard (§ 165.110(d)) to indicate that finished product that tests positive for *E. coli* will be deemed adulterated under section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(3)). In addition, FDA amended the Current Good Manufacturing Practices (CGMP) regulations for bottled water in part 129 by requiring that source water from other than a public water system (PWS) be tested at least weekly for total coliform. If any coliform organisms are detected in the source water, the bottled water manufacturers are required to determine whether any of the coliform organisms are *E. coli*. Source water found to contain *E. coli* is not considered water of a safe, sanitary quality and would be unsuitable for bottled water production. Before a bottler may use source water from a source that has tested positive for *E. coli*, a bottler must take appropriate measures to rectify or otherwise eliminate the cause of the contamination. A source previously found to contain *E. coli* will be considered negative for *E. coli* after five samples collected over a 24-hour period from the same sampling site are tested and found to be *E. coli* negative.

Description of Respondents: The respondents to this proposed information collection are domestic and foreign bottled water manufacturers that sell bottled water in the United States.

In the **Federal Register** of May 29, 2009 (74 FR 25752), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
§§ 129.35(a)(3)(i) and 129.80(h)	319 (bottlers subject to source water and finished product testing)	6	1,914	0.08	153
§§ 129.35(a)(3)(i) and 129.80(h)	2.5 (bottlers conducting secondary testing of source water)	5	12	0.08	1
§§ 129.35(a)(3)(i) and 129.80(h)	2.5 (bottlers rectifying contamination)	3	7.5	0.25	2
§ 129.80(g) and (h)	95 (bottlers testing finished product only)	3	285	0.08	23
Total Annual Burden					179

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