

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.

Substances Prohibited From Use in Animal Food or Feed; Animal Protein Prohibited in Ruminant Feed-21 CFR 589.2000(e)(1)(iv)—(OMB Control Number 0910-0339)—Extension

This information collection was established because epidemiological evidence gathered in the United Kingdom suggested that bovine spongiform encephalopathy (BSE), a progressively degenerative central nervous system disease, is spread to ruminant animals by feeding protein derived from ruminants infected with BSE. This regulation places general requirements on persons that manufacture, blend, process, and distribute products that contain or may contain protein derived from mammalian tissue, and feeds made from such products.

Specifically, this regulation requires renderers, feed manufacturers, and others involved in feed and feed ingredient manufacturing and distribution to maintain written procedures specifying the cleanout

procedures or other means, and specifying the procedures for separating products that contain or may contain protein derived from mammalian tissue from all other protein products from the time of receipt until the time of shipment. These written procedures are intended to help the firm formalize their processes, and then to help inspection personnel confirm that the firm is operating in compliance with the regulation. Inspection personnel will evaluate the written procedure, and confirm it is being followed when they are conducting an inspection.

These written procedures must be maintained as long as the facility is operating in a manner that necessitates the record, and if the facility makes changes to an applicable procedure or process the record must be updated. Written procedures required by this section shall be made available for inspection and copying by the Food and Drug Administration.

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 recordkeeping	Total hours
Maintaining written procedures (§ 589.2000 (e)(1)(iv))	400	1	400	14	5600

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

Dated: May 10, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-11633 Filed 5-15-13; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0557]

Agency Information Collection Activities; Proposed Collection; Comment Request; Postmarket Surveillance

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 information collection requirements for postmarket surveillance of medical devices.

DATES: Submit either electronic or written comments on the collection of information by July 15, 2013.

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: Daniel Gittleston, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, daniel.gittleston@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.

Postmarket Surveillance—21 CFR Part 822 (OMB Control Number 0910–0449)—Extension

Section 522 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360I) authorizes the FDA to require a manufacturers to conduct postmarket surveillance (PS) of any device that meets the criteria set forth in the statute. The PS regulation establishes procedures that FDA uses to approve and disapprove PS plans. The regulation provides instructions to manufacturers so they know what information is

required in a PS plan submission. FDA reviews PS plan submissions in accordance with part 822 (21 CFR part 822) in §§ 822.15 through 822.19 of the regulation, which describe the grounds for approving or disapproving a PS plan. In addition, the PS regulation provides instructions to manufacturers to submit interim and final reports in accordance with § 822.38. Respondents to this collection of information are those manufacturers who require postmarket surveillance of their products.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity/21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Postmarket surveillance submission (§§ 822.9 and 822.10)	131	1	131	120	15,720
Changes to PS plan after approval (§ 822.21)	15	1	15	40	600
Changes to PS plan for a device that is no longer marketed (§ 822.28)	80	1	80	8	640
Waiver (§ 822.29)	1	1	1	40	40
Exemption request (§ 822.30)	16	1	16	40	640
Periodic reports (§ 822.38)	131	3	393	40	15,720
Total					33,360

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

Explanation of Reporting Burden Estimate: The burden captured in table 1 of this document is based on the data available in FDA’s internal tracking

system. Sections 822.26, 822.27, and 822.34 do not constitute information collection subject to review under the PRA because it entails “no burden other

than that necessary to identify the respondent, the date, the respondent’s address, and the nature of the instrument” (5 CFR 1320.3(h)(1)).

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

Activity/21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Manufacturer records (§ 822.31)	131	1	131	20	2,620
Investigator records (§ 822.32)	393	1	393	5	1,965
Total					4,585

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

Explanation of Recordkeeping Burden Estimate: FDA expects that at least some of the manufacturers will be able to satisfy the PS requirement using information or data they already have. For purposes of calculating burden, however, FDA has assumed that each PS order can only be satisfied by a 3-year clinically-based surveillance plan, using three investigators. These estimates are based on FDA’s knowledge and experience with postmarket surveillance.

Dated: May 13, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–11697 Filed 5–15–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0545]

Agency Information Collection Activities; Proposed Collection; Comment Request; Infant Formula Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing an opportunity for public comment on our proposed collection of

certain information. 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 invites comments on the information collection provisions of our infant formula regulations, including infant formula labeling, quality control procedures, notification requirements, and recordkeeping.

DATES: Submit either electronic or written comments on the collection of information by July 15, 2013.