Substances Prohibited From Use in Animal Food or Feed—21 CFR Part 589 (OMB Control Number 0910–0627—Revision)

This regulation prohibits the use of certain cattle origin materials in the food or feed of all animals to help prevent the spread of bovine spongiform encephalopathy (BSE) in United States' cattle. BSE is a progressive and fatal neurological disorder of cattle that results from an unconventional transmissible agent. BSE belongs to the family of diseases known as transmissible spongiform encephalopathies (TSEs). All TSEs affect the central nervous system of infected animals. These measures will further strengthen existing safeguards against BSE.

Description of Recordkeeping for Respondents: Rendering facilities, medicated feed manufacturers, livestock feeders.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section 589.2001; substances prohibited from use in animal food or feed	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeper	Total hours	Operating and maintenance costs
589.2001(c)(2)(vi) and (c)(3)(i)	175	1	175	20	3,500	$59,500
589.2001(c)(2)(ii)	50	1	50	20	1,000	17,000
589.2001(c)(3)(i)(A)	175	1	175	26	4,550	80,580
Total					9,050	157,080

[1] There are no capital costs associated with this collection of information.

The number of recordkeepers times the number of records per recordkeeper equals total annual records. Total annual records times average burden per recordkeeper equals total hours.

Description of Respondents for Reporting: The final regulation on BSE (73 FR 22720) included a provision that exempts cattle materials prohibited in animal feed (CMPAF) from designated countries from the prohibition on its use in animal feed. A foreign country seeking this designation will submit a written request to FDA that includes a variety of information about the country's BSE status (§ 589.2001(f)). During the past 6 years, FDA received 2 requests from countries to be exempted from CMPAF restrictions.

FDA estimates the reporting burden for this information collection as follows:

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section 589.2001(f)	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per respondent	Total hours
One-time (initial) burden	1	1	1	80	80
Burden from future review	1	1	1	26	26

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

One-Time (initial) Reporting Burden

There will be a one-time burden to countries that apply to FDA seeking to be designated as not subject to restrictions applicable to CMPAF. We estimate that each country that applies for an exclusion will spend 80 hours putting information together to submit to FDA. Table 2 row 1 presents the one-time burden for the exclusion. (See final BSE regulation at 73 FR 22754).

Recurring Burden

Countries that successfully petition FDA to be designated as exempt from certain BSE-related restrictions applicable to animal feed will be subject to future review by FDA to ensure that their designation remains appropriate. As part of this process, FDA may ask designated countries from time to time to confirm that their BSE situation and the information submitted by them in support of their original application remains unchanged. We assume it will take FDA and the designated country undergoing a review in the future about one third the time and effort it did when the information was submitted. Table 2 row 2 presents the expected recurring burden.

Dated: November 17, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–27518 Filed 11–20–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0535]

Agency Information Collection Activities; Proposed Collection; Comment Request; Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body

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 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. This notice invites comments on the collection of information associated with the submission of notifications of health claims or nutrient content claims based on authoritative statements of scientific bodies of the U.S. Government.

DATES: Submit either electronic or written comments on the collection of information by January 20, 2015.

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: 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: 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, we are publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, we invite comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of our functions, including whether the information will have practical utility; (2) the accuracy of our 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.

Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body—(OMB Control Number 0910–0374)—Extension

Section 403(r)(2)(G) and (r)(3)(C) of the Federal Food, Drug and Cosmetic Act (the FD&C Act) (21 U.S.C. 343(r)(2)(G) and (r)(3)(C)), as amended by the FDA Modernization Act of 1997, provides that any person may market a food product whose label bears a nutrient content claim or a health claim that is based on an authoritative statement of a scientific body of the U.S. Government or the National Academy of Sciences (NAS). Under this section of the FD&C Act, a person that intends to use such a claim must submit a notification of its intention to use the claim 120 days before it begins marketing the product bearing the claim. In the **Federal Register** of June 11, 1998 (63 FR 32102), we announced the availability of a guidance entitled ''Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body.'' The guidance provides the Agency's interpretation of terms central to the submission of a notification and the Agency's views on the information that should be included in the notification. We believe that the guidance will enable persons to meet the criteria for notifications that are established in section 403(r)(2)(G) and (r)(3)(C) of the FD&C Act. In addition to the information specifically required by the FD&C Act to be in such notifications, the guidance states that the notifications should also contain information on analytical methodology for the nutrient that is the subject of a claim based on an authoritative statement. We intend to review the notifications we receive to ensure that they comply with the criteria established by the FD&C Act.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Section of the FD&C Act	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
403(r)(2)(G) (nutrient content claims)	1	1	1	250	250
403(r)(2)(C) (health claims)	1	1	1	450	450
Guidance for Notifications	2	1	2	1	2
Total					702

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

These estimates are based on our experience with health claims, nutrient content claims, and other similar notification procedures that fall under our jurisdiction. To avoid estimating the number of respondents as zero, we estimate that there will be one or fewer respondents annually for nutrient content claim and health claim notifications. We estimate that we will receive one nutrient content claim notification and one health claim notification per year over the next 3 years.

Section 403(r)(2)(G) and (r)(3)(C) of the FD&C Act requires that the notification include the exact words of the claim, a copy of the authoritative statement, a concise description of the basis upon which such person relied for determining that this is an authoritative statement as outlined in the FD&C Act, and a balanced representation of the scientific literature relating to the relationship between a nutrient and a disease or health-related condition to which a health claim refers or to the nutrient level to which the nutrient content claim refers. This balanced representation of the scientific literature is expected to include a bibliography of the scientific literature on the topic of the claim and a brief, balanced account or analysis of how this literature either supports or fails to support the authoritative statement.

Since the claims are based on authoritative statements of a scientific body of the U.S. Government or NAS, we believe that the information that is required by the FD&C Act to be submitted with a notification will be readily available to a respondent. However, the respondent will have to collect and assemble that information. Based on communications with firms that have submitted notifications, we estimate that one respondent will take 250 hours to collect and assemble the information required by the statute for a nutrient content claim notification. Further, we estimate that one respondent will take 450 hours to collect and assemble the information required by the statute for a health claim notification.

Under the guidance, notifications should also contain information on analytical methodology for the nutrient that is the subject of a claim based on an authoritative statement. The guidance applies to both nutrient content claim and health claim notifications. We have determined that this information should be readily available to a respondent and, thus, we estimate that it will take a respondent 1 hour to incorporate the information into each notification. We expect there will be two respondents for a total of 2 hours.

Dated: November 17, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–27517 Filed 11–20–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA 1999–D–3528 (Formerly Docket No. 1999D–5046)]

Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture; Guidance for Industry'' dated December 2014. The guidance document provides manufacturers of licensed whole blood and blood components intended for transfusion or for further manufacture, including source plasma, with recommendations concerning submission of changes to an approved biologics license application (BLA). The guidance document also provides manufacturers of licensed whole blood and blood components recommendations in connection with the applicability and content of comparability protocols and labeling changes. The guidance applies to the manufacture and distribution of licensed products. The guidance announced in this notice finalizes the draft guidance of the same title dated June 2013 and supersedes the document of the same title dated July 2001 (July 2001 guidance).

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the 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 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 guidance document.

Submit electronic comments on the 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: Jonathan McKnight, 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 document entitled ''Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture; Guidance for Industry'' dated December 2014. The guidance document provides manufacturers of licensed whole blood and blood components intended for transfusion or for further manufacture, including source plasma, with recommendations concerning submission of changes to an approved BLA in accordance with the requirements under Title 21 of the Code of Federal Regulations 601.12 (21 CFR 601.12). The guidance document also provides manufacturers of licensed whole blood and blood components with recommendations in connection with the applicability and content of comparability protocols under § 601.12(e) and labeling changes under § 601.12(f). Frequently, a manufacturer of a licensed product determines that it is appropriate to make a change in its product, production process, quality controls, equipment, facilities, responsible personnel, or labeling as documented in its approved BLA(s). Section 601.12 states the requirements to report such changes for licensed biological products to FDA.

The recommendations contained in the guidance document reflect current FDA and industry experience with reporting changes to an approved application, including reporting the implementation of new technologies. The recommendations have been revised for reporting categories for certain changes to an approved application that were in the July 2001 guidance based on the experience gained over the last decade.

In the **Federal Register** of May 31, 2013 (78 FR 32668), FDA announced the availability of the draft guidance of the same title dated June 2013. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. In response to comments, the guidance includes the addition of numerous appendices with tables to highlight the appropriate reporting categories related to certain manufacturing changes. The guidance announced in this notice finalizes the draft guidance dated June 2013.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents 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 requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

The 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