

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours) ²	Total hours
190.6	55	1	55	20	1,100

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

We believe that there will be minimal burden on the industry to generate data to meet the requirements of the premarket notification program because we are requesting only that information that the manufacturer or distributor should already have developed to satisfy itself that a dietary supplement containing a new dietary ingredient is in full compliance with the FD&C Act. In the past, commenters argued that our burden estimate is too low. We revisited this issue and believe their burden estimate included the time it takes to research and generate safety data for a new dietary ingredient. However, sec. 190.6(a) requires each manufacturer or distributor of a dietary supplement containing a new dietary ingredient, or of a new dietary ingredient, to submit notification of the basis for their conclusion that said supplement or ingredient will reasonably be expected to be safe. Section 190.6 requests simply the extraction and summarization of the safety data that should have already been developed by the manufacturer or distributor. Thus, we estimate that extracting and summarizing the relevant information from the company's files, and presenting it in a format that will meet the requirements of section 413 of the FD&C Act will require a burden of approximately 20 hours of work per submission.

We estimate that 55 respondents will submit one premarket notification each and that it will take a respondent 20 hours to prepare the notification, for a total of 1,100 hours. The estimated number of premarket notifications and hours per response is an average based on our experience with notifications received during the last 3 years and information from firms that have submitted recent premarket notifications.

Dated: August 20, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0973]

Agency Information Collection Activities; Proposed Collection; Comment Request; Animal Feed Network (Pet Event Tracking Network and LivestockNET)—State, Federal Cooperation To Prevent Spread of Pet Food and Animal Feed Related Diseases

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 the paperwork burden to the public of the Animal Feed Network, which includes the Pet Event Tracking Network (PETNet) and LivestockNET, for reporting of pet food or animal feed related instances, respectively.

DATES: Submit either electronic or written comments on the collection of information by October 25, 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:

Domini Bean, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50-400T, Rockville, MD

20850, 301-796-5733, domini.bean@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.

Pet Event Tracking Network—State, Federal Cooperation To Prevent Spread of Pet Food Related Diseases—and Livestock.NET—21 U.S.C. 342, 21 U.S.C. 343, Section 1002(b) of the FDA Amendments Act of 2007 (Pub. L. 110-85, 121 Stat. 823) (2007)—OMB Control Number 0910-0680

On August 1, 2011, the Pet Event Tracking Network (PETNet) was launched by FDA and its partners in the

Partnership for Food Protection (PFP). PETNet is a secure, Web-based network that allows information to be exchanged more freely and efficiently between FDA and other Federal and State regulatory agencies. PETNet allows the exchange of information about pet food related incidents, such as illness associated with the consumption of pet food or pet food product defects. PETNet is only accessible by government employees with membership rights, and each member has equal access to the data in the system. At its launch, the system had over 200 members representing 4 Federal agencies, all 50 states, and 3 U.S. territories. Using the shared information, State and Federal agencies can work together to quickly determine if regulatory actions are needed to prevent or quickly limit adverse effects associated with pet food products.

Since its launch, PETNet has seen increased usage among members. Two years following the launch of the system, there have been reports entered by two Federal agencies and multiple states. Approximately 60 percent of the entries are from Federal agency members and 40 percent by State agency members. The majority of entries in PETNet are associated with dog food products, followed by cat food products, products affecting species "other" than those available in the drop down menu choices, and small mammal products. As familiarity with PETNet has increased, there has been increased usage and entries from members.

PETNet was originally developed for pet animals only, but after its initial launch in 2011, there have been ongoing

requests to expand the system to include livestock animals, aquaculture species, and horses. Such an early alert system does not currently exist to share information related to illness associated with consumption of adulterated food or product defects for these species. LivestockNET has been developed to serve as a similar early alert system for feed-related illness and product defects associated with feed for livestock animals, aquaculture species, and horses.

LivestockNET and PETNet will be Web-based portals with the same functionality, but the questions asked for each portal will be specific for each. Users of the individual portals are expected to be the same officials from Federal, State, and Territorial agencies. Because of the similarity of the portals and the intended audience for both, the two individual portals will be housed in an overall system titled the Animal Feed Network. PETNet and LivestockNET will be able to be accessed individually in the Animal Feed Network, once the user logs in to the system.

Use of the Animal Feed Network, including the reporting of incidents by non-FDA members, will continue to be voluntary. The Animal Feed Network is a Web-based system, based in a proprietary system using CORESHIELD technology, and will be accessible only to members via password. PETNet and LivestockNET will make use of standardized electronic forms that have been custom developed for the individual portals. The two forms share the following common data elements, the majority of which are drop down

menu choices: Product details (name of feed, lot code, product form, and the manufacturer or distributor/packer (if known)), the species affected, number of animals exposed to the product, number of animals affected, body systems affected, product problem/defect, date of onset or the date product problem was detected, the State where the incident occurred, the origin of the information, whether there are supporting laboratory results, and contact information for the reporting member (i.e., name, telephone number will be captured automatically when member logs in to the system). For the LivestockNET form, additional data elements specific to livestock animals will be captured: Product details (indication of whether the feed is a medicated feed, product packaging, and intended purpose of the feed), class of the animal species affected, and production loss. For PETNet, the only additional data field is the animal life stage. The form would be filled out and submitted by a member in the specified portal of the Animal Feed Network. Once the entry is submitted, it will be available to other members. Thus, the information will be entered and received by Animal Feed Network members in as close to real time as possible. FDA and the PFP have designed the form itself to contain only the essential information necessary to alert Animal Feed Network members about animal feed and pet food related incidents.

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

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21 U.S.C. section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
21 U.S.C. 342, 21 U.S.C. 343, Section 1002(b) of the FDA Amendments Act of 2007/PETNet.	20	5	100	0.25 (15 minutes)	25
Ibid./LivestockNET portal	20	5	100	0.25 (15 minutes)	25
Total Hours	50

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

FDA estimates that each State will report to the Animal Feed Network (i.e., fill out the PETNet or LivestockNET form to alert other members about a pet food or animal food related incident, respectively) approximately 5 times per year for each portal. This estimate represents the maximum number of reports that FDA expects a State to submit in a year, and in many cases the number of reports submitted by a State

will probably be far less. FDA believes that, given the PETNet form has 15 items and the LivestockNET form has 19 items, with most being drop down fields and not all fields being required for submission, 15 minutes is a sufficient amount of time to complete the form. State regulatory officials responsible for animal feed and pet food already possess computer systems and have the Internet access necessary to participate

in the Animal Feed Network, and thus there are no capital expenditures associated with the reporting.

Regarding recordkeeping, State regulatory officials who report in the Animal Feed Network receive the reportable information from consumers in their States in the course of their customary and regular duties. Further, these individuals already maintain records of such consumer complaints in the course of their duties, which are

sufficient for the purposes of reporting in the PETNet and LivestockNET portals of the Animal Feed Network. Therefore, FDA believes that the proposed collection of information does not have additional recordkeeping requirements.

Dated: August 20, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0724]

Documents to Support Submission of an Electronic Common Technical Document; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability on the Agency Web site of revised final versions of the following four documents that support making regulatory submissions in electronic format using the electronic Common Technical Document (eCTD) specifications: “The eCTD Backbone Files Specification for Module 1,” version 2.2 (which includes the U.S. regional document type definition (DTD), version 3.2); “The Comprehensive Table of Contents Headings and Hierarchy,” version 2.2; “Specifications for eCTD Validation Criteria,” version 3.0; and “Example Submissions using eCTD Backbone Files Specification for Module 1,” version 1.2. Technical files that support these documents are also available on the Agency Web site. A complete summary of the revisions made is included in the updated documents. FDA estimates it will be able to receive submissions utilizing Module 1 Specifications 2.2 by June 2014, and will give 30 days’ advance notice to industry.

ADDRESSES: Submit written requests for single copies of the documents to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993-0002 or Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-

addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the documents.

FOR FURTHER INFORMATION CONTACT:

Constance Robinson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 1105, Silver Spring, MD 20993, 301-796-1065, email: constance.robinson@fda.hhs.gov; or Joseph Montgomery, Center for Biologics Evaluation and Research, Food and Drug Administration, 11400 Rockville Pike, HFM-165, Rm. 4155, Rockville, MD 20857, 301-827-1332, email: joseph.montgomery@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The eCTD is an International Conference on Harmonisation (ICH) standard based on specifications developed by ICH and its member parties. FDA’s Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) have been receiving submissions in the eCTD format since 2003, and the eCTD has been the standard for electronic submissions to CDER and CBER since January 1, 2008. The majority of new electronic submissions are now received in eCTD format. Since adoption of the eCTD standard, it has become necessary to update the administrative portion of the eCTD (Module 1) to reflect regulatory changes, provide clarification of business rules for submission processing and review, refine the characterization of promotional marketing and advertising material, and facilitate automated processing of submissions. FDA previously announced availability of final versions of technical documentation in a **Federal Register** notice dated February 13, 2013 (Docket No. FDA-2011-N-0724). The Agency has revised the final documentation and is making available revised versions of the following documents:

- “The eCTD Backbone Files Specification for Module 1, version 2.2,” which provides specifications for creating the eCTD backbone file for Module 1 for submission to CDER and CBER (This document should be used in conjunction with the guidance for industry *Providing Regulatory Submissions in Electronic Format—Human Pharmaceutical Applications and Related Submissions Using the eCTD Specifications*, which will be revised as part of the implementation of the updated eCTD backbone files

specification (<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072349.pdf>)).

- “The Comprehensive Table of Contents Headings and Hierarchy,” version 2.2, which reflects updated headings that are specified in the document entitled “The eCTD Backbone Files Specification for Module 1,” version 2.2

- “Specifications for eCTD Validation Criteria,” version 3.0

- “Example Submissions using eCTD Backbone Files Specification for Module 1,” version 1.2

Supporting technical files are being made available on the Agency Web site.

A complete summary of the revisions made are included in the updated documents. The revisions include the following:

eCTD Backbone Files Specification for Module I

- changed DTD version references from 3.1 to 3.2, where applicable
- replaced the copy of DTD Version 3.1 in Appendix I with DTD Version 3
- revised text, revised Table 1, and added Table 13 to indicate the new required attribute *material-id* and the new optional attribute *issue-date* which applies to m1-15-2-1

The Comprehensive Table of Contents Headings and Hierarchy

- added two new attributes for 1.15.2.1

Specifications for eCTD Validation Criteria

- incorporated changes to US eCTD Module 1

Example Submissions using eCTD Backbone Files Specification for Module 1

- modified example 7 to reference the Form FDA 356h in the Admin section
- modified examples 13 through 17 to reference the material-id and issue date attributes as applicable, and include the Promotional Labeling and Advertising Regulatory Contact

FDA is not prepared at present to accept submissions utilizing this new version of the eCTD Backbone Files Specification for Module 1, version 2.2, because eCTD software vendors need time to update their software to accommodate this information and because its use will require software upgrades within the Agency. FDA estimates it will be able to receive submissions utilizing Module 1 Specifications 2.2 by June 2014, and will give 30 days advance notice to industry.