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.

In the **Federal Register** of August 26, 2013 (78 FR 52774), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although four comments were received, none were responsive to the four collection of information topics solicited and therefore will not be discussed in this document.

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

TABLE 1—ESTIMATED REPORTING BURDEN [1]

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 member 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 five times per year for each portal. This estimate represents the maximum number of reports that FDA expects will be submitted in a year, and in many cases the number of reports submitted by a member 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: February 20, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–04012 Filed 2–24–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1619]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements

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 March 27, 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 0910–0606. 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, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *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 (CGMP) in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements—21 CFR Part 111 (OMB Control Number 0910–0606)—Extension

On October 25, 1994, the Dietary Supplement Health and Education Act (DSHEA) (Pub. L. 103–417) was signed into law. DSHEA, among other things, amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by adding section 402(g) of the FD&C Act (21 U.S.C. 342(g)). Section 402(g)(2) of the FD&C Act provides, in part, that the Secretary of Health and Human Services may, by regulation, prescribe good manufacturing practices for dietary supplements. Section 402(g) of the FD&C Act also stipulates that such regulations will be modeled after CGMP regulations for food and may not impose standards for which there are no current, and generally available, analytical methodologies. Section 402(g)(1) of the FD&C Act states that a dietary supplement is adulterated if ''it has been prepared, packed, or held under conditions that do not meet current good manufacturing practice regulations.'' Under section 701(a) of the FD&C Act (21 U.S.C. 371), FDA may issue regulations necessary for the efficient enforcement of the FD&C Act. In the **Federal Register** of June 25, 2007 (72 FR 34752) (the June 25, 2007, final rule), FDA published a final rule that established, in part 111 (21 CFR part 111), the minimum CGMP necessary for activities related to manufacturing, packaging, labeling, or holding dietary supplements to ensure the quality of the dietary supplement.

Records are an indispensable component of CGMP. The records required by FDA's regulations in part 111 provide the foundation for the planning, control, and improvement processes that constitute a quality control system. Implementation of these processes in a manufacturing operation serves as the backbone to CGMP. The records show what is to be manufactured; what was, in fact, manufactured; and whether the controls that the manufacturer put in place to ensure the identity, purity, strength, and composition and limits on contaminants and to prevent adulteration were effective. Further, records will show whether and what deviations from control processes occurred, facilitate evaluation and corrective action concerning these deviations (including, where necessary, whether associated batches of product should be recalled from the marketplace), and enable a manufacturer to assure that the corrective action was effective. In addition, by establishing recordkeeping requirements, FDA can ensure that industry follows CGMP during manufacturing, packaging, labeling, or holding operations. The regulations in part 111 establish the minimum manufacturing practices necessary to ensure that dietary supplements are manufactured, packaged, labeled, or held in a manner that will ensure the quality of the dietary supplements during manufacturing, packaging, labeling, or holding operations.

The recordkeeping requirements of the regulations include establishing written procedures and maintaining records pertaining to: (1) Personnel; (2) sanitation; (3) calibration of instruments and controls; (4) calibration, inspection, or checks of automated, mechanical, or electronic equipment; (5) maintaining, cleaning, and sanitizing equipment and utensils and other contact surfaces; (6) water used that may become a component of the dietary supplement; (7) production and process controls; (8) quality control; (9) components, packaging, labels, and product received for packaging and labeling; (10) master manufacturing and batch production; (11) laboratory operations; (12) manufacturing operations; (13) packaging and labeling operations; (14) holding and distributing operations; (15) returned dietary supplements; and (16) product complaints.

Description of Respondents: Manufacturers, dietary supplement manufacturers, packagers and repackagers, labelers and re-labelers, holders, distributors, warehousers, exporters, importers, large businesses, and small businesses engaged in the dietary supplement industry.

The recordkeeping requirements of the regulations in part 111 are set forth in each subpart. In table 1 we list the annual burdens associated with recordkeeping, as described in the June 25, 2007, final rule. For some provisions listed in table 1, we did not estimate the number of records per recordkeeper because recordkeeping occasions consist of frequent brief entries of dates, temperatures, monitoring results, or documentation that specific actions were taken. Information might be recorded a few times a day, week, or month. When the records burden involves frequent brief entries, we entered 1 as the default for the number of records per recordkeeper. For example, many of the records listed under § 111.35 in table 1, such as § 111.35(b)(2) (documentation, in individual equipment logs, of the date of the use, maintenance, cleaning, and sanitizing of equipment), involve many short sporadic entries over the course of the year, varying across equipment and plants in the industry. We did not attempt to estimate the actual number of recordkeeping occasions for these provisions, but instead entered an estimate of the average number of hours per year. We entered the default value of 1 as the number of records per recordkeeper for these and similar provisions. For § 111.35, the entry for number of records is 1 as a default representing a large number of brief recordkeeping occasions.

In many rows of table 1, we list a burden under a single provision that covers the written procedures or records described in several provisions. For example, the burden of the batch production records listed in table 1 under § 111.260 includes the burden for records listed under § 111.255 because the batch production records must include those records.

The number of records for batch production records (and other records kept on a batch basis in table 1) equals the annual number of batches. The estimated burden for records kept by batch includes both records kept for every batch and records kept for some, but not all, batches. We use the annual number of batches as the number of records that will not necessarily be kept for every batch, such as test results or material review and disposition records, because such records are part of records, if they are necessary, that will be kept for every batch.

In the **Federal Register** of December 19, 2013 (78 FR 76836), 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 recordkeeping	Total hours
111.14, records of personnel practices, including documentation of training	15,000	4	60,000	1	60,000
111.23, records of physical plant sanitation practices, including pest control and water quality	15,000	1	15,000	0.2	3,000
111.35, records of equipment and utensils calibration and sanitation practices	400	1	400	12.5	5,000
111.95, records of production and process control systems	250	1	250	45	11,250
111.140, records that quality control personnel must make and keep	240	1163	279,120	1	279,120
111.180, records associated with components, packaging, labels, and product received for packaging and labeling as a dietary supplement	240	1163	279,120	1	279,120
111.210, requirements for what the master manufacturing record must include	240	1	240	2.5	600
111.260, requirements for what the batch record must include	145	1408	204,160	1	204,160
111.325, records that quality control personnel must make and keep for laboratory operations	120	1	120	15	1,800
111.375, records of the written procedures established for manufacturing operations	260	1	260	2	520
111.430, records of the written procedures for packaging and labeling operations	50	1	50	12.6	630
111.475, records of product distribution and procedures for holding and distributing operations	15,000	1	15,000	0.4	6,000
111.535, records for returned dietary supplements	110	4	440	13.5	5,940
111.570, records regarding product complaints	240	600	144,000	0.5	72,000
Total					929,140

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

The average burden per recordkeeping estimates in table 1 are based on those in the June 25, 2007, final rule, which were based on our institutional experience with other CGMP requirements and on data provided by Research Triangle Institute in the ''Survey of Manufacturing Practices in the Dietary Supplement Industry'' cited in that rule.

The estimates in table 1 of the number of firms affected by each provision of part 111 are based on the percentage of manufacturers, packagers, labelers, holders, distributors, and warehousers that reported in the survey that they have not established written standard operating procedures or do not maintain records that were later required by the June 25, 2007, final rule. Because we do not have survey results for general warehouses, we entered the approximate number of facilities in that category for those provisions covering general facilities. For the dietary supplement industry, the survey estimated that 1,460 firms would be covered by the final rule, including manufacturers, packagers, labelers, holders, distributors, and warehousers. The time estimates include the burden involved in documenting that certain requirements are performed and in recordkeeping. We used an estimated annual batch production of 1,408 batches per year to estimate the burden of requirements that are related to the number of batches produced annually, such as § 111.260, ''What must the batch production record include?'' The estimate of 1,408 batches per year is near the midpoint of the number of annual batches reported by survey firms.

The length of time that CGMP records must be maintained is set forth in § 111.605. Table 1 reflects the estimated burdens for written procedures, record maintenance, periodically reviewing records to determine if they may be discarded, and for any associated documentation for that activity for records that are required under part 111. We have not included a separate estimate of burden for those sections that require maintaining records in accordance with § 111.605, but have included those burdens under specific provisions for keeping records. For example, § 111.255(a) requires that the batch production records be prepared every time a batch is manufactured, and § 111.255(d) requires that batch production records be kept in accordance with § 111.605. The estimated burdens for both § 111.255(a) and (d) are included under § 111.260 (what the batch record must include).

Dated: February 20, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–04014 Filed 2–24–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–N–0037]

Agency Information Collection Activities; Proposed Collection; Comment Request; Animal Drug User Fee Act Waivers and Reductions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.