important to project monitoring and success. For all FY14 FOAs, ANA proposes to use the following criteria values:

Need for Assistance—10 points;
Outcomes Expected—25 points;
Project Approach—30 points;
Objective Work Plan—25 points
Budget and Budget Justification—10 points

3. *Scoring Guidance:* ANA proposes to provide guidance to reviewers to utilize the table below when allocating points for applications in order to ensure consistency and equivalence in the scoring among different panels and panel reviewers. ANA proposes to add the following table to all FY14 FOAs:

Excellent	93–100
Very Good	86–92
Good	78–85
Fair	70–77
Needs Significant Improvement	0–69

L. *ANA Internal Review of Proposed Projects:* ANA proposes to clarify the language in *Section V.2. Review and Selection Process* of the FOAs to clarify of the scope of ANA's discretion to be exercised in making funding decisions as follows:

Based on the ranked order of applications, ANA staff will perform an internal review and analysis of the applications ranked highest as a result of the panel's review and scoring in order to determine the application's consistency with the purposes of NAPA, all relevant statutory and regulatory requirements, and the requirements of the relevant FOA. ANA's Commissioner has discretion to make all final funding and award decisions. In the exercise of such discretion the Commissioner will consider:

- Whether the project, as determined based on ANA's administrative and programmatic expertise, does not to further the purpose of the funding opportunity as described in *Section I. Funding Opportunity Description.*
- Whether the project is determined to be unlikely to be successful or cost effective based on the application submitted for evaluation in response to *Section IV.2. Project Description and Budget and Budget Justification.*
- Whether the project allows any one community, or region, to receive a disproportionate share of the funds available for award.
- Whether the projects is essentially identical or similar in whole or in part to previously funded projects proposed by the same applicant or activities or projects proposed by a consortium that duplicate activities for which any consortium member also receives or has received funding from ANA.
- Whether the project provides couples or family counseling activities that are medically-based.
- Whether the project originated and was designed by consultants, who have provided a major role for themselves in the performance of the project, and who are not members of the applicant organization, tribe, or village.
- Whether the project contains contingent activities that may impede, or indefinitely delay, the progress of the project.
- Whether the project has the potential to cause unintended harm to participants, or that could negatively impact the safety or privacy of individuals.
- Whether the project may be used for the purpose of providing loan capital. Federal funds awarded under this FOA may not be used for the purpose of providing loan capital. This restriction is not related to loan capital authorized under Sec. 803A of NAPA [42 U.S.C. 2991b-1(a)(1)] for the purpose of the Hawaiian Revolving Loan fund.
- Whether the project includes human subject research as defined at 45 CFR 45.102 (d) and (f).
- Whether the project is duplicative of projects funded by other federal agencies.

Please note: The funding restriction applied in prior years' FOAs on ''Projects that seek to revive Native American languages that do not have any living speakers'' has been removed from the above list. Projects with this focus are now eligible to receive funding under Language Preservation and EMI FOAs.

M. *Reporting:* ANA proposes to change the frequency of reporting requirements from quarterly to semi-annual for the Objective Progress Reports (OPR) and Financial Status Reports (FSR). Therefore, grantees will be required to submit an OPR and an FSR every 6 months instead of every 3 months. Please note that grantees will still be required to submit a Federal Financial Report—Federal Cash Transaction Report SF–425 (FFR–FCTR) to the Division of Payment Management (DPM) on a quarterly basis.

Statutory Authority: This notice for public comment is required by Section 814 of the Native American Programs Act of 1974 (NAPA), as amended.

Lillian A. Sparks Robinson,

Commissioner, Administration for Native American.

[FR Doc. 2013–30192 Filed 12–18–13; 8:45 am]

BILLING CODE 4184–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1619]

Agency Information Collection Activities; Proposed Collection; 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 or we) 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 invites comments on the information collection provisions of FDA's regulations regarding current good manufacturing practice (CGMP) for dietary supplements.

DATES: Submit either electronic or written comments on the collection of information by February 18, 2014.

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, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *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, 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.

Current Good Manufacturing Practice 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 methodology. 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 of this document 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 of this document, 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 of this document) 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.

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	Avg. burden per record-keeping	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 of this document 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 SOPs 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 of this document 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: December 13, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–30185 Filed 12–18–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1588]

Agency Information Collection Activities; Proposed Collection; Comment Request; Tobacco Products, Exemptions From Substantial Equivalence Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the