ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Responses per respondent	Average burden per response (in hours)	Total burden hours
General Resident	In-depth Interview/phone	600	1	1.5	900
	Screener	1,200	1	6/60	120
Health care provider	In-depth Interview/phone	200	1	.5	100
	Screener	400	1	6/60	40
Community Leader	In-depth Interview/phone	200	1	1.5	300
	Screener	400	1	6/60	40
Elected Official	In-depth Interview/phone	100	1	.5	50
Industry	In-depth Interview/phone	100	1	.5	50
Total					1,600

Dated: September 21, 2010.

Maryam I. Daneshvar,

Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 2010–24181 Filed 9–24–10; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0355]

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 October 27, 2010.

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: Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

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 in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements (OMB Control Number 0910–0606)—Extension

On October 25, 1994, the Dietary Supplement Health and Education Act (DSHEA) (Public Law 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 (the Secretary) may, by regulation, prescribe good manufacturing practices for dietary supplements. Section 402(g) of the FD&C Act also stipulates that such regulations shall be modeled after current good manufacturing practices (CGMPs) 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. FDA published a final rule on June 25, 2007 (72 FR 34752) (the final rule) that established, in part 111 (21 CFR part 111), the minimum CGMPs 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 CGMPs. 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 CGMPs. The records will show what is to be manufactured; what was, in fact, manufactured; and whether the controls that the manufacturer put in place to control 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 requiring records, FDA will be able to ensure that industry follows CGMPs 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 records requirements of the regulations include written procedures and 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.

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. In the table, where the same records are mentioned in more than one provision of a subpart, we list the burden under the provisions corresponding to the heading in the final rule, "Under this subpart, what records must you make and keep?" For some provisions listed in table 1, we did not estimate the annual frequency of recordkeeping 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 one as the default for the annual frequency of recordkeeping. 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 annual frequency of recordkeeping for these and similar provisions. For § 111.35, the entry for annual frequency 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 annual frequency 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 frequency for 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 July 14, 2010 (75 FR 40840), 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	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
111.14	15,000	4	60,000	1	60,000
111.23	15,000	1	15,000	0.2	3,000
111.35	400	1	400	12.5	5,000
111.95	250	1	250	45	11,250
111.140	240	1,163	279,120	1	279,120
111.180	240	1,163	279,120	1	279,120
111.210	240	1	240	2.5	600
111.260	145	1,408	204,160	1	204,160
111.325	120	1	120	15	1,800
111.375	260	1	260	2	520
111.430	50	1	50	12.6	630
111.475	15,000	1	15,000	0.4	6,000
111.535	110	4	440	13.5	5,940
111.570	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 burden estimates in table 1 of this document are based on those in the final rule, which were based on our institutional experience with other CGMP requirements and on data provided by Research Triangle Institute (RTI) 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 (SOPs) or do not maintain records that were later required by the 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: September 21, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–24105 Filed 9–24–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0434]

Draft Guidance for Industry: Acidified Foods; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled "Guidance for Industry: Acidified Foods." The draft guidance, when finalized, will complement FDA's regulations regarding acidified foods, including regulations for specific current good manufacturing practice (CGMP), establishment registration, and process filing. The draft guidance is intended to assist commercial food processors in determining whether their food products are subject to these regulations. The draft guidance also is intended to assist processors of acidified foods in ensuring safe manufacturing, processing, and packing processes and in employing appropriate quality control procedures. Under the draft guidance, processors of non-acidified foods (e.g., some acid foods or fermented foods) who are not subject to the acidified food regulations may choose to voluntarily register and file scheduled processes with us using existing forms (Forms FDA 2541 and 2541a). If such processors voluntarily submit this information, we plan to make the results of any FDA evaluation of the information available to our investigators, e.g., during inspections of food facilities and during evaluations of foods offered for import.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments concerning the draft guidance by December 27, 2010. Submit either electronic or written comments concerning the collection of information provisions by December 27, 2010.

ADDRESSES: Submit electronic comments on the draft guidance and the proposed collection of information provisions 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. Submit written requests for single copies of the draft guidance entitled "Guidance for Industry: Acidified Foods" to the Office of Food Safety, Center for Food Safety and Applied Nutrition (HFS–302), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–436–2669. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT:

With regard to the draft guidance document: Michael Mignogna, Center for Food Safety and Applied Nutrition (HFS–302), Food and Drug Administration, 5100 Paint Branch Parkway, College Park, MD 20740, 301–436–1565.

With regard to the information collection: Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20857, 301–796–3793.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled "Guidance for Industry: Acidified Foods." The draft guidance, when finalized, will complement FDA's regulations regarding acidified foods, including regulations for specific CGMP, establishment registration, and process filing. The draft guidance is intended to assist commercial food processors in determining whether their food products are subject to these regulations. Under the draft guidance, processors of acid foods and fermented foods who conclude that such foods they produce are not also acidified foods[1] may voluntarily register and file scheduled processes with us using existing forms (Forms FDA 2541 and 2541a) for acidified foods. Processors of

[1] Fermented foods, such as some kinds of sauerkraut, cucumber pickles, and green olives, are low-acid foods subjected to the action of acid-producing microorganisms to reduce the pH of the food. Not all fermented foods meet the definition of "acidified foods" in 21 CFR 114.3(b). However, some fermented foods that contain acid are also acidified foods. We also note that fermented dairy products, such as yogurt, belong to a separate category that is not relevant to the fermented foods that are discussed in this guidance.