SUPPORTING STATEMENT

Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements
FINAL RULE

A. Justification

1. Need and Legal Basis

Section 402(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 342 (g)) gives the Food and Drug Administration (FDA) explicit authority to issue a rule establishing Current Good Manufacturing Practice for dietary supplements. Section 402(g)(1) of the 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." Section 402(g)(2) of the act authorizes FDA to, by regulation, "prescribe good manufacturing practices for dietary supplements." Under section 701(a) of the act (21 U.S.C. 371), FDA may issue regulations necessary for the efficient enforcement of the act.

Records are an indispensable component of CGMP. The records required by this final rule 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 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, the agency will be able to ensure that firms follow CGMPs so that they ensure the quality of their dietary supplements during manufacturing, packaging, labeling, or holding operations. The final rule establishes 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.

2. Information Users

Dietary supplement manufacturers, packagers and re-packagers, labelers, holders, distributors, and warehouses will collect this information. The information will be used to establish current good manufacturing practices for dietary supplements and ensure that they are manufactured, packaged, labeled, and held in a manner that will ensure product quality and that the dietary supplement is packaged and labeled as specified in the master manufacturing record. The final rule includes written procedures and records pertaining to: (1) personnel; (2)sanitation; (3) calibration of instruments and controls; (4) calibration, inspection, or checks of automatic, 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.

This is a new collection of information.

3. Improved Information Technology

The facilities are free to use whatever method they wish, including automated, electronic, mechanical, other technological collection techniques, or other forms of information technology.

4. Duplication of Similar Information

The final rule does not represent a duplication of effort.

5. Small Businesses

The final rule will have a significant economic impact on a substantial number of small businesses. Small businesses with fewer than 20 employees will be given an additional 2 years to comply with the final rule. Small businesses with 20 to 499 employees will be given an additional year to comply with the final rule.

6. Less Frequent Collection

Less frequent collections of information would reduce the documentation that is intended to ensure that dietary supplements are manufactured, packaged, labeled, and held in a manner that will ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record.

7. Special Circumstances

No special circumstances are associated with the collection of information.

8. Federal Register Notice/Outside Consultation

FDA published a proposed rule on March 13, 2003 in the **Federal Register** Volume 68, No. 49, page 12158. The agency received more than 400 comments in response to the proposal. No comments were received on the Paperwork Reduction Act analysis of the proposed rule. FDA held public stakeholder meetings on April 29, 2003 in College park, MD, and on May 6, 2003 in Oakland, CA. The agency held a public meeting using a satellite downlink on May 9, 2003, with viewing sites at our district and regional offices throughout the country.

9. Payment/Gift to Respondent

No payment or gifts are associated with this collection of information.

10. Confidentiality

All information obtained by the agency will be reviewed in accordance with the guidelines set forth in the FDA Freedom of Information Regulations (21 CFR Part 20).

11. Sensitive Questions

This information collection does not contain questions of a sensitive nature (e.g., those regarding sexual behavior and attitudes, religious beliefs, etc).

12. Burden Estimate (Total Hours and Wages)

The respondents to this collection of information are firms in the dietary supplement industry, including dietary supplement manufacturers, packagers and re-packagers, holders, labelers and re-labelers, distributors, warehouses, exporters, importers, large businesses, and small businesses.

The total estimated burden imposed by this collection of information is 156,430 hours to establish written procedures and 929,140 hours for annual recordkeeping.

Table 1.--Estimated One-Time Burden to Establish Written Procedures[1]

21 CFR Section	Number of Recordkeepers	Annual Frequency per Recordkeeping	Total Records	Hours per Record	Total Hours[2]
111.14	15,000	1	15,000	3.6	54,000
111.23	15,000	1	15,000	1	15,000

21 CFR Section	Number of Recordkeepers	Annual Frequency per Recordkeeping	Total Records	Hours per Record	Total Hours[2]
111.35	400	1	400	36	14,400
111.95	250	1	250	68	17,000
111.140	300	1	300	10.7	3, 210
111.180	200	1	200	10	2,000
111.210	250	1	250	12	3,000
111.325	150	1	150	45	6,750
111.375	260	1	260	9	2,340
111.430	250	1	250	12.6	3,150
111.475	15,000	1	15,000	2.1	31,500
111.535	200	1	200	6	1,200
111.570	240	1	240	12	2,880
Total					156,430

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

Table 2.--Estimated Annual Recordkeeping Burden[1]

21 CFR Section	Number 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	1163	279,120	1	279,120
111.180	240	1163	279,120	1	279,120
111.210	240	1	240	2.5	600
111.260	145	1408	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

21 CFR Section	Number of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
Total					929,140

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

The recordkeeping requirements of the final rule are set forth in each subpart. FDA's estimates of the one-time burdens associated with establishing written procedures are shown in Table 1. FDA's estimates of the annual burdens associated with recordkeeping are shown in Table 2. In each 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, "Under this subpart, what records must you make and keep?" For some provisions listed in Table 2, we did not estimate the annual frequency of recordkeeping because recordkeeping occasions consist of frequent briefs 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 final § 111.35 in Table 2, such as final § 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 final § 111.35, the entry for annual frequency is 1 as a default representing a large number of brief recordkeeping occasions.

In many rows of Tables 1 and 2, we list a burden under a single provision that covers the written procedures or records described in several provisions. The burden of the master manufacturing record listed in Table 1 under final § 111.210 includes the burden for final § 111.205 because the master manufacturing record must include those written procedures. Similarly, the burden of the batch production records listed in Table 2 under final § 111.260 includes the burden for records listed under final § 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 2) equals the annual number of batches. We use that 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 that will be kept for every batch. The estimated burden for records kept by batch includes both records kept for every batch and records kept for some but not all batches.

The estimates in both tables of the number of firms affected by each provision of the rule are based on the percentage of manufacturers, packagers, labelers, holders, distributors, and warehouses that reported in the survey that they have not established written SOPs or do not maintain records that would be required under 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 this final rule, including manufacturers, packagers, labelers, holders, distributors, and warehouses. 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 final § 111.260, "What must 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 final § 111.605. Tables 1 and 2 reflect 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 will be required under part 111. We have not included a separate estimate of burden for those sections that require maintaining records in accordance with final § 111.605, but have included those burdens under specific provisions for keeping records. For example, final § 111.255(a) requires that the batch production records be prepared every time a batch is manufactured, and final § 111.255(d) requires that batch production records be kept in accordance with final § 111.605. The estimated burdens for both §§ 111.255(a) and (d) are included under final § 111.260.

We estimate the cost to respondents for the one-time burden to establish written procedures (156,430 hours) to be about $4 million. This estimate uses an average wage of $26 per hour for employees engaged in establishing written procedures.

We estimate the annual cost to respondents for the recordkeeping burden (929,140 hours) to be about $24 million. This estimate uses an average wage of $26 per hour for employees responsible for recordkeeping.

13. Capital Costs (Maintenance of Capital Costs)

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

14. Cost to Federal Government

This collection of information will not lead to any costs to the Federal government.

15. Program or Burden Changes

This is a new collection; there are therefore no program changes or adjustments.

16. Publication or Burden Changes

The results of this information collection will not be published.

17. Display of OMB Approval Date

We are not seeking approval to not display the expiration date for OMB approval of the information collection.

18. Exceptions to the "Certification for Paperwork Act Submissions"

No exceptions to the certification statement were identified.