

that you keep records established in accordance with proposed § 111.125. Proposed § 111.125 would establish general recordkeeping requirements and tell you how long you must keep certain records. As we have stated several times in this document, we determine CGMP compliance by conducting inspections. Records, therefore, enable you to show, and for us to determine, how you complied with the CGMP requirements.

Proposed § 111.125(a) would apply to all records covered by the proposed rule and would require that you keep those records for 3 years beyond the date of manufacture of the last batch of dietary ingredients or dietary supplements associated with those records. Retention for 3 years beyond the date of manufacture would be appropriate for followup of consumer complaints received during the marketing period.

Proposed § 111.125(b) would deal with the form in which you keep records. The proposal would allow you to keep records required under this part as original records, as true copies (such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records), or as electronic records. If you use reduction techniques, such as microfilming, the proposal would require that you make suitable reader and photocopying equipment readily available to us. If you use electronic records, the proposal would require that you comply with part 11 (our requirements for electronic records).

Proposed § 111.125(c) would require that you make your records available for inspection and copying by us when requested. We sometimes need to copy records when our field inspectors need guidance or additional expertise from our headquarters staff; if we were unable to copy records, our inspections would become more complicated and longer in duration, particularly if the inspection involved a complex scientific or technical issue that normally would be handled at FDA headquarters.

IV. Statement Concerning the Use of Plain Language

In response to the June 1, 1998, White House Presidential Memorandum on Plain Language, we drafted this proposed rule in plain language. Plain language is intended to help readers find requirements quickly and understand them easily. To do that, we have reorganized sections modeled after existing regulations and rewrote the paragraphs using:

- Short sections, paragraphs, sentences, and words to speed up reading and enhance understanding;

- Sections as questions and answers to focus sections better; and
- Personal pronouns to reduce passive voice and draw readers into the text.

In some cases, we modeled a proposed provision after an existing regulation, but wrote the proposed rule using plain language techniques. We invite the public to comment on the plain language techniques used in this proposed rule. In developing your comments, please consider addressing the following points:

- Do you like the proposed rule's appearance?
- Do plain language techniques make the document easier to read and understand? and
- Do you have other suggestions to improve the format?

V. Paperwork Reduction Act of 1995

This proposed rule contains information collection requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). A description of these requirements is given below with an estimate of the annual recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

We invite comments on: (1) Whether the proposed collection of information is necessary for the proper performance of our functions, including whether the information will have practical utility; (2) the accuracy of our 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 the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Current Good Manufacturing Practice in Recordkeeping and Reporting for Dietary Ingredients and Dietary Supplements.

Description: Section 402(g) of the act gives us explicit authority to issue a rule regulating conditions for manufacturing, packaging, and holding 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 us to, by regulation,

“prescribe good manufacturing practices for dietary supplements.” Other relevant legal authority is discussed in section II of this document.

For this proposed CGMP rule for dietary ingredients and dietary supplements, recordkeeping is necessary to provide the type of documentation that would demonstrate that dietary ingredients and dietary supplements are manufactured, packaged, and held under the conditions that would be required under the proposed CGMP regulations. Under section 701(a) of the act, we may issue regulations necessary for the efficient enforcement of the act. If you did not keep records, for example, documenting practices performed during previous production runs, it would be difficult for us to determine whether, as stated under section 402(g)(1) of the act, the dietary supplement had been manufactured, packaged, and held under CGMPs. By requiring records, we will be able to ensure that you follow CGMPs and that your dietary supplements are not adulterated and misbranded during manufacturing, packaging, or holding operations.

The proposed rule would establish the minimum manufacturing practices necessary to ensure that dietary supplements are manufactured, packaged, or held in a manner that will not adulterate and misbrand the dietary ingredients or dietary supplements.

The proposed regulations would impose requirements for: (1) Personnel, (2) physical plants, (3) equipment and utensils, (4) production and process controls, (5) holding and distributing, (6) consumer complaints, and (7) records and recordkeeping.

We are proposing recordkeeping requirements that include records pertaining to: (1) Calibration of instruments and controls; (2) automatic, mechanical, or electronic equipment calibration, inspection, or checks; (3) production and process controls; (4) quality control; (5) receiving components, dietary supplements, packaging, and labels; (6) master manufacturing and batch production; (7) packaging and label operations; (8) returned dietary ingredients or dietary supplements; and (9) consumer complaints.

Description of Respondents: Dietary ingredient manufacturers, dietary supplement manufacturers, packagers and repackagers, distributors, warehouse, exporters, importers, large businesses, and small businesses.

We estimate the burden of this collection of information as follows: