

firms varied in size and were located in several parts of the country.

We found an array of manufacturing, packaging, and holding practices in the firms. The practices included the following:

- Using CGMPs similar to those included in the ANPRM;
- Using automatic systems to quarantine, segregate, approve, and release inventory;
- Following written procedures;
- Having quality control units with the responsibility and authority outlined in the ANPRM;
- Performing one or more tests on dietary ingredients and dietary supplements to determine the identity, purity, quality, strength, and composition;
- Verifying the reliability of suppliers' certifications; and
- Documenting and maintaining records for certain procedures, such as master and batch production, quality control and laboratory operations, distribution, and processing consumer complaints.

D. Food Advisory Committee Report

In February 1998, the Food Advisory Committee (FAC) established a Dietary Supplement Working Group to consider what constitutes adequate testing for identity of different dietary ingredients and what records are necessary to demonstrate that CGMPs are maintained throughout the manufacturing and distribution process. The working group issued a report that discussed the selection of the most appropriate and reliable identity test and the general principles for consideration in setting performance standards for such tests (Ref. 4). The report also identified the types of records that would be necessary to demonstrate that CGMPs are maintained throughout the manufacturing and distribution process. On June 25, 1999, the working group presented its report, in draft form, during an FAC public meeting. We received public comments during and after the June 25, 1999, public meeting.

Although this proposal does not address dietary ingredient identity testing in the same detail as the working group's report, we considered the report in developing requirements for identity testing and CGMP records requirements in this proposal. The working group's report may be useful in developing industry guidance to supplement a CGMP regulation for dietary ingredients and dietary supplements. We discuss dietary ingredient and dietary supplement identity testing and recordkeeping for CGMP proposed

requirements in more detail later in this document.

E. FDA's Decision To Propose a Rule

This proposed regulation, which sets forth proposed CGMPs for dietary ingredients and dietary supplements, is part of our overall strategy for regulating dietary supplements in a manner that promotes and protects the public health. Before drafting the proposal, FDA considered public comment in response to the ANPRM and to public meetings, observations at site visits to dietary supplement manufacturers, and advisory group reports. In drafting this proposal, FDA used, in part, the industry coalition outline that was published as an ANPRM (62 FR 5700) in which the industry adopted broad provisions beyond those found in part 110 (21 CFR part 110). FDA's purpose at this proposed rule stage is to present a broad enough scope so that it may receive comment on the depth and breadth of what should be considered by the agency in developing a final rule. Our intent is to provide the proper balance of regulation so that dietary ingredients and dietary supplements are manufactured in a manner to prevent adulteration using recognized scientific principles and both industry and consumer expectations that are reasonable and appropriate. Therefore, FDA seeks comment on whether each of the proposed provisions are necessary to ensure the safety and quality of dietary ingredients and dietary supplements and whether they are adequate to protect the public health. In addition, we seek comment on whether there are certain provisions that are not proposed but that may be necessary. Comments should include justification for why provisions may or may not be necessary, including supporting data where appropriate. If comments assert that certain provisions are not necessary, comments should include an explanation on how, in the absence of the requirement, one can ensure that there would be adequate protection of the public health when there is risk of adulteration. Comments also should address whether the gains to consumers in product safety and quality are warranted. Moreover, assuming that this proposal does advance the public health, comments should address whether there is any reason to apply different requirements, including greater or lesser requirements on small firms as compared to larger firms and the rationale for doing so. Finally, comments should address the agency's legal authority to issue these regulations.

In deciding whether to propose CGMP regulations for dietary supplements, we asked ourselves:

- Why Are CGMP regulations needed?
- How will CGMP regulations take into account technical feasibility? and
- How can FDA help industry achieve compliance with CGMPs?

1. Why Are CGMPs Needed?

CGMP regulations for dietary ingredients and dietary supplements are necessary to promote and protect the public health. In addition, CGMP regulations would benefit consumers economically and would benefit industry.

a. *CGMPs help protect the public health.* The dietary supplement industry is one of the fastest growing product areas that FDA regulates. In 1999, *Prevention* magazine conducted a survey entitled "Consumer Use of Dietary Supplements" (Ref. 5). The survey used data from telephone interviews with a nationally-representative sample of 2,000 adults living in households with telephones in the continental United States. The telephone interviews were done in April and May, 1999. Using population estimates based on the Census Bureau's March 1998 Current Population Survey Estimates, the survey stated that approximately 186,014,712 adults live in the households with telephones in the United States and that an estimated 158.1 million of these Americans in households with telephones use dietary supplement products. These consumers spend approximately \$8.5 billion a year on dietary supplements. The survey also found that:

- Only 41 percent of the surveyed consumers who use vitamins and minerals think they are very safe and only 50 percent think they are somewhat safe;
- Only 24 percent of the surveyed consumers who use herbal products think they are very safe; and only 53 percent think they are somewhat safe; and
- Twelve percent of the surveyed consumers who have used dietary supplements say they have experienced side effects or adverse reactions from their use of dietary supplements.

The survey also found strong public support for increased Government regulation of dietary supplements; 74 percent of the surveyed consumers reported that they think that the Government should be more involved in ensuring that these products are safe and do what they claim to do.

However, unlike other major product areas, there are no FDA regulations that