

industry, CGMPs based on HACCP principles may provide a more flexible and less burdensome regulatory framework for manufacturers and distributors than the approach set out in the industry submission.

Most comments opposed basing a CGMP regulation for dietary ingredients and dietary supplements on HACCP principles. Most comments supported applying traditional CGMP requirements on manufacturing, packaging, and holding to dietary ingredients and dietary supplements. In general, the comments that opposed requiring HACCP for dietary ingredients and dietary supplements asserted that: (1) A HACCP program would not be appropriate because HACCP focuses on microbial contamination of products that provide a favorable environment for growth of microbes that may be present, and these hazards are not a major concern for dietary supplements; (2) CGMPs are the best means of assuring the safety, quality, and composition of dietary ingredients and dietary supplements; (3) HACCP is not required for the food industry as a whole; and (4) HACCP would provide minimal incremental value at significant additional costs.

Other comments opposed mandatory HACCP regulations for dietary ingredients and dietary supplements, but said manufacturers could implement voluntarily HACCP instead. One comment, which supported voluntary implementation of HACCP, wanted manufacturers to be exempt from having to disclose HACCP records to any Federal agency.

HACCP principles can be applied to a broad range of manufacturing practices and HACCP principles are not solely focused on microbial contamination, but instead, are intended to identify and appropriately control steps in manufacturing where any type of adulteration can occur. Nevertheless, after considering the comments, we have decided to propose a CGMP approach for dietary ingredients and dietary supplements. We believe that CGMPs would establish a system of controls that, given the variations in size, technological sophistication, and regulatory experience among dietary ingredient and dietary supplement firms, would create a strong regulatory foundation throughout the industry.

You may voluntarily choose to implement a HACCP plan that meets the requirements of the National Advisory Committee on Microbiological Criteria for Foods, however, proposed part 111 would still apply to you (Ref. 42). Any HACCP plans that also are intended to meet the records requirements under

proposed part 111 would be treated as records under this proposal.

*Question 9.* We invited comment on whether broad CGMP regulations will be adequate, or whether it will be necessary to address the operations of particular segments of the dietary supplement industry.

Most comments supported broad CGMP regulations covering all segments of the dietary supplement industry instead of specific regulations tailored to distinct segments of the industry. One comment stated that the differences between distinct segments of the dietary supplement industry, such as manufacturers of raw materials or distributors of finished products, are no more pronounced than similar segments in the food industry. Another comment stated that having numerous CGMPs could subject raw materials and dietary ingredients to multiple CGMPs, thus making manufacturing operations more complex. This comment also questioned whether issuing multiple regulations is necessary or economically justified in an era of limited corporate and government regulatory resources. Other comments emphasized the importance of ensuring that all dietary supplement manufacturers (*i.e.*, both small and large manufacturers, and foreign manufacturers planning to import dietary supplements into the United States) follow the same CGMP requirements.

In contrast, some comments supported drafting regulations for particular segments of the dietary supplement industry. One comment stated that certain stages of the manufacturing process, such as the distribution of raw dietary ingredients, should be more strictly and comprehensively regulated than other stages because potential hazards are more prevalent during these manufacturing stages. The comment stated that conversely, the holding, distribution, and sale of a finished dietary supplement may require less comprehensive regulations because they are subject to fewer potential hazards. Other comments supported different levels of safety testing for different types of dietary supplement products. For example, some comments said that products such as melatonin and dehydroepiandrosterone resemble drugs, so we should require safety testing in animals and humans and impose druglike CGMP requirements for manufacturing. Another comment stated that less stringent CGMPs would be appropriate for herbal dietary supplements because they have long histories of food use and safety.

We agree that some manufacturing operations are subject to greater hazards than others, and have drafted the proposed rule accordingly. For example, there are microbial hazards associated with raw botanicals. To address these hazards, the proposal would require that you perform tests on the botanicals. On the other hand, there are fewer hazards associated with holding and distributing finished dietary supplements, so the proposal would impose less comprehensive requirements for holding and distributing operations.

We are persuaded by the comments that support a broad CGMP regulation as preferable to multiple regulations focused on particular segments of the industry. We agree with the comments that multiple regulations might be confusing and burdensome, especially to firms that manufacture products that fall into multiple categories. For instance, it would be easier for regulated firms and for us if firms were required to adhere to one set of CGMP requirements rather than follow, for example, one set of CGMP requirements for vitamins and a different set of CGMP requirements for minerals.

We also recognize, though, that there may be some reasons to treat different types of dietary ingredients or dietary supplements differently in specific instances. For example, it may be appropriate to require one type of test for confirming the identity of amino acids and another type of test for confirming the identity of herbals. However, for the reasons discussed previously, we are proposing to establish one set of broad CGMP regulations for all types of products. Because we recognize that one set of specific requirements may not be appropriate for all types of dietary ingredients and dietary supplements, we have proposed regulations that allow manufacturers to develop practices to meet CGMP requirements. Depending on our experience with this proposed rule, we will consider whether we need to reevaluate our decision to establish one set of requirements for all dietary ingredients and dietary supplements.

We agree with the comments that the proposed rule should not make any distinction between dietary ingredients or dietary supplements made in the United States and those made in a foreign country. The proposed rule would require that foreign firms that want to export dietary ingredients and dietary supplements to the United States manufacture, package, and hold dietary ingredients and dietary supplements consistent with proposed part 111. Moreover, under this proposed rule, if a U.S. firm contracts with a