

Exports

This proposed rule would require additional controls to be kept throughout the production and distribution chain for the manufacture of dietary ingredients and dietary supplements. The additional control costs would increase the total costs of production and distribution for all of the regulated products, including products sold within the U.S. and across national borders. These increased costs will be largely passed on to consumers in the form of higher prices, which will tend to reduce the quantity demanded of the regulated products. The increased prices of U.S. exports could reduce the quantity of U.S. exports demanded, particularly in comparison with exports from countries that do not implement similar regulations. We expect this effect to be insignificant, because under the proposed rule the increases in the price of United States exports (and resulting decreases in quantity demanded) would be quite small.

VIII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We consulted with seven State officials to make a tentative determination about whether this proposed rule would have federalism implications. Based on this consultation, it does not appear that this proposed rule has federalism implications. In addition, we sent a letter on March 7, 2000, to elected State officials and their representative organization to notify them that our unified agenda was published on November 22, 1999, and identified this proposed CGMP rule as a rule that would publish in the year 2000. In that letter, we solicited comments on any federalism implications that this proposed rule may have. To date, no responses have been received to our solicitation. After publishing this proposed rule, FDA will send a letter to elected State officials and their representative organization requesting consultation about any federalism implications. We invite comment on our tentative determination that this proposed rule does not have federalism implications, and therefore, does not contain policies that have substantial direct effects on the States, or on the distribution of power and responsibilities among the various levels of government.

IX. Request for Comments

Interested persons may submit to the Dockets Management Branch (*see ADDRESSES*) written or electronic

comments regarding this document. Submit a single copy of electronic comments to <http://www.fda.gov/dockets/ecomments> or two hard copies of any written comments, except that individuals may submit one hard copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

X. References

- We have placed the following references on display in the Dockets Management Branch (*see ADDRESSES*). You may see them between 9 a.m. and 4 p.m., Monday through Friday.
1. Section 2, "Findings," Dietary Supplement Health and Education Act, Pub. L. 103-417, pp. 4325-4326, October 25, 1994.
 2. "Manufacturing Practices for Nutritional Supplements," *United States Pharmacopeia*, 12601 Twinbrook Pkwy., Rockville, MD 20852, General Chapter 2750, 2186-2192, and 2834, 1993.
 3. "NNFA Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Supplements," *National Nutritional Foods Association*, 3931 MacArthur Blvd., suite 101, Newport Beach, CA 92660, 1999.
 4. "Draft Report of the Food Advisory Committee Dietary Supplement Working Group on Ingredient Identity Testing and Records and Retention," FDA Food Advisory Committee Dietary Supplement Working Group, Center for Food Safety and Applied Nutrition, FDA, June 25, 1999.
 5. "Consumer Use of Dietary Supplements," *Rodale Press*, 733 Third Ave., New York, NY 10017, 2000.
 6. Slifman, N. R., W. R. Obermeyer, B. K. Aloï, S. M. Musser, W. A. Correll, S. M. Cichowicz, J. M. Betz, and L. A. Love, "Contamination of Botanical Dietary Supplements by *Digitalis Lanata*," *New England Journal of Medicine*, 339:12, pp. 806-811, 1998.
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13. Kumar, S. and A. K. Roy, "Occurrence of Aflatoxin in Some Liver Curative Herbal Medicines," *Letters in Applied Microbiology*, 17, pp. 112-114, 1993.
14. Kumar, S. and G. Prasad, "Efficacy of Medicinal Plant (*Andrographis peniculata*) Extract on Aflatoxin Production and Growth of *Aspergillus flavus*," *Letters in Microbiology* 15, pp. 131-132, 1992.
15. "Adverse Events Associated with Ingestion of Gamma-Butyrolactone: Minnesota, New Mexico, and Texas, 1998-1999," *MMWR Weekly*, 48:07, pp. 137-140, February 26, 1999.
16. FDA Establishment Inspection Report, Ducoa Co., CFN #1944182, August 31, 1998 and September 1, 1998.
17. FDA Health Hazard Evaluation, Classification, and FDA Enforcement Report for Firm-Initiated Recall—Lead, U.S. FDA Recall #F-006-5 and #F-137/145-5, 1994.
18. FDA Health Hazard Evaluation, Classification, and FDA Enforcement Report for Firm-Initiated Recall *Salmonella*, U.S. FDA Recall #F-164/171-8, 1988.
19. FDA Health Hazard Evaluation, Classification, and FDA Enforcement Report for Firm-Initiated Recall—*Klebsiella Pneumonia*, U.S. FDA Recall #F-522-0, 1990.
20. FDA Health Hazard Evaluation, Classification, and FDA Enforcement Report for Firm-Initiated Recall—*Botulism*, U.S. FDA Recall #F-563/564-9, 1989.
21. FDA Health Hazard Evaluation, Classification, and FDA Enforcement Report for Firm-Initiated Recall—Glass Fragments, U.S. FDA Recall #F-540-3, 1993.
22. FDA Health Hazard Evaluation, Classification, and FDA Enforcement Report for Firm-Initiated Recall Super-Potent Vitamin A, U.S. FDA Recall #F-157/158-5, 1994.
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24. FDA Health Hazard Evaluation, Classification, and FDA Enforcement Report for Firm-Initiated Recall—Super-