DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Ch. I

62 FR 24619
5.6.97

[Docket No. 96N–0417]

RIN 0910–AA59

Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Supplements

6/6/97

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it is extending to June 6, 1997, the comment period for the advance notice of proposed rulemaking on current good manufacturing practice (CGMP) in manufacturing, packing, or holding dietary supplements that published in the **Federal Register** of February 6, 1997 (62 FR 5700). This action is being taken in response to several requests from interested persons for an extension of the comment period on this document to allow a more thorough development of comments on FDA's request for information on whether requirements for manufacturing and handling dietary ingredients and dietary supplements may be addressed by a regulation based on the principles of Hazard Analysis and Critical Control Points (HACCP).

DATES: Written comments by June 6, 1997.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Robert J. Moore, Center for Food Safety and Applied Nutrition (HFS–456), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4605.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 6, 1997 (62 FR 5700), FDA published an advance notice of proposed rulemaking on CGMP in manufacturing, packing, or holding dietary supplements (Docket No. 96N–0417). Interested persons were given until May 7, 1997, to comment on the advance notice of proposed rulemaking.

FDA has received requests from two manufacturers, and two trade organizations representing manufacturers, of dietary supplements for an extension of the comment period. Three requests asked that the agency extend the comment period in order to provide more time for interested parties to develop comments on FDA's request for information on whether requirements for manufacturing and handling dietary ingredients and dietary supplements may be adequately addressed by a regulation based on the principles of HACCP. The requests stated that many dietary supplement manufacturers were not familiar with the HACCP concept, and additional time was needed to fully understand HACCP and its applicability to the development of CGMP for dietary supplements. After careful consideration of the requests submitted to the agency, FDA has decided to grant an extension of the comment period until June 6, 1997.

Interested persons may, on or before June 6, 1997, submit to the Dockets Management Branch (address above) written comments regarding this advance notice of proposed rulemaking. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the appropriate docket number found in brackets in the

heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 23, 1997

April 28, 1997

William B. Schultz

William B. Schultz
Deputy Commissioner for Policy

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Michael W. Bell