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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 111

[Docket No. 96N-0417]

Dietary Supplements; Center for Food Safety and Applied Nutrition; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to solicit comments that will assist the Center for Food Safety and Applied Nutrition (CFSAN) to understand the economic impact that any proposal to establish current good manufacturing practices (CGMP's) regulations for dietary supplements may have on small businesses in the dietary supplement industry. This meeting is intended to give interested persons, including small businesses, an opportunity to comment on the economic impact that such a proposal may have on small businesses.

DATES: The public meeting will be held on Monday, July 12, 1999, from 7 p.m. to 9 p.m. You must register by July 7, 1999. You may submit written comments until August 12, 1999.

ADDRESSES: The public meeting will be held at the Flamingo Hotel, The Carson City II Room, 3555 Las Vegas Blvd., Las Vegas, NV. Submit written comments to the Dockets Management Branch (HFA-305), Docket No. 96N-0417, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Two copies of any comments are to be submitted, except that individuals may submit one copy.

FOR FURTHER INFORMATION CONTACT: Peter J. Vardon, Center for Food Safety and Applied Nutrition (HFS-726), Food and Drug Administration, 330 C St. SW., Washington, DC 20204, 202-205-5329, FAX 202-260-0794, or e-mail pvardon@bangate.fda.gov.

If you would like to attend the public meeting, you should register by July 7, 1999, by faxing or e-mailing your name, title, firm name, address, and telephone number to Peter Vardon (address above).

There is no registration fee for this public meeting, but early registration is suggested because space may be limited.

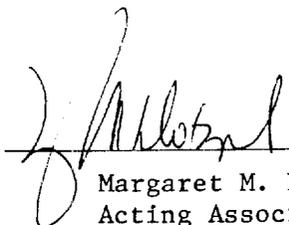
SUPPLEMENTARY INFORMATION: This public meeting will provide an opportunity for an open discussion of the manufacturing practices of small businesses in the dietary supplement industry. The meeting is intended to be one of a series intended to give all interested parties an opportunity to comment on the economic effects of a possible proposed regulation on CGMP's in the dietary supplement industry. This public meeting is also intended to fulfill part of the outreach requirement of Small Business Regulatory Enforcement Fairness Act of 1996. The agenda will include topics regarding the small business entities' manufacturing practices and standard operating procedures for: (1) Personnel, (2) buildings and facilities, (3) equipment, (4) lab operations, (5) production and process controls, and (6) warehousing, distribution and post-distribution of raw, intermediate and final products. The meeting will also include a discussion about the verification of the identity, purity, and composition of dietary supplements and dietary supplement ingredients.

FDA encourages individuals or firms with relevant data or information to present such information at the meeting or in written comments to the record.

You may request a transcript of the public meeting from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15 working days after the meeting. The transcript of the public meeting and

submitted comments will be available for public examination at the Dockets Management Branch (address above) between 9 a.m. and 4 p. m., Monday through Friday.

Dated: 6-11-99
June 11, 1999



Margaret M. Dotzel
Acting Associate Commissioner for
Policy Coordination

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL



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