



August 8, 2003

MEMORANDUM TO: Division of Dockets Management (HFA-305)

SUBJECT: Extension of Comment Period on Docket No. 96N-0417 (Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements)

Please include this memorandum in docket number 96N-0417. See 21 CFR 10.40(b).

This memorandum confirms that the comment period for the subject docket, which was scheduled to close on August 11, 2003, will be kept open until September 9, 2003. The Food and Drug Administration (FDA) has received requests from the Council for Responsible Nutrition (CRN), the American Herbal Products Association (AHPA), and the Utah Natural Products Alliance (UNPA) for an extension of the comment period on the subject proposed rule. FDA will extend the comment period for these organizations for 29 days. Consistent with 21 CFR 10.40(b)(3)(ii), the agency is providing notice of this 29-day extension through this memorandum filed with the Dockets Management Branch. FDA notes that, as part of their requests for extension of the comment period, the three trade associations referenced a Freedom of Information Act request they submitted to FDA to obtain spreadsheets related to the economic analysis of the proposed rule. These spreadsheets contain the same data and information (only in a different format) already provided to the public in the administrative record at the time the proposed rule was published. Thus, the agency does not believe that these spreadsheets present any new information.

Due to the late request to extend the comment period and the late request for the data and information in a different format, the agency does not believe that CRN, AHPA, and UNPA would have sufficient time to complete their review of the economic analysis. Thus, the agency is agreeing to an additional 29-day extension of the comment period for CRN, AHPA, and UNPA to have a feasible time to review and comment on the agency's economic analysis. The agency does not believe it is necessary to extend this comment period to the general public since the agency does not believe that the spreadsheets constitute new information that is necessary to complete the administrative record.

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