where any deletion is made. Neither an estimation of the volume of requested material nor an indication of the amount of information deleted shall be included in a response if doing so would harm an interest protected by the exemption in 5 U.S.C. 552(b) pursuant to which the material is withheld.

(c) If no response is made within twenty (20) working days or any extension thereof, the requester can consider his or her administrative remedies exhausted and seek judicial relief in a United States District Court as specified in 5 U.S.C. 552(a)(4)(B).

7. Section 1015.9 is amended by revising paragraphs (e)(5) and (g)(1) to read as follows:

§ 1015.9 Fees for production of records.

(5) Computerized records: $0.10 per page of computer printouts or, for central processing, $0.32 per second of central processing unit (CPU) time, for printer, $10.00 per 1,000 lines; and for computer magnetic tapes or discs, direct costs.

(g) * * *

(1) Interest will be charged on amounts billed, starting on the 31st day following the day on which the requester received the bill. Interest will be at the rate prescribed in 31 U.S.C. 3717.

§ 1015.10 Commission report of actions to Congress.

On or before February 1 of each year, the Commission shall submit a report of its activities with regard to freedom of information requests during the preceding fiscal year to the Attorney General of the United States. This report shall include:

(b)(1) The number of appeals made by persons under such provisions, the result of such appeals, and the reason for the action upon each appeal that results in a denial of information; and

(2) a complete list of all statutes that the Commission relies upon to withhold information under such provisions, a description of whether a court has upheld the decision of the Commission to withhold information under each such statute, and a concise description of the scope of any information withheld.

(c) The number of requests for records pending before the Commission as of September 30 of the preceding year, and the median number of days that such requests had been pending before the Commission as of that date.

(d) The number of requests for records received by the Commission and the number of requests which the Commission processed.

(e) The median number of days taken by the Commission to process different types of requests.

(f) The total amount of fees collected by the Commission for processing requests.

(g) The number of full-time staff of the Commission devoted to processing requests for records under such provisions, and the total amount expended by the Commission for processing such requests.


Sadie E. Dunn,
Secretary, Consumer Product Safety Commission.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Ch. I

[Docket No. 96N–0417]

RIN 0910–AA59

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

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. 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 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.


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.


William B. Schultz,
Deputy Commissioner for Policy.

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