DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 210 and 211

[Docket No. 95N–0362]

RIN 0910–AA45

Current Good Manufacturing Practice; Proposed Amendment of Certain Requirements for Finished Pharmaceuticals; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to September 30, 1996, the comment period for the proposed rule that would revise the current good manufacturing practice (CGMP) regulations for finished pharmaceuticals. The proposed rule was published in the Federal Register of May 3, 1996 (61 FR 20104). The proposal would clarify certain manufacturing, quality control, and documentation requirements and would ensure that the regulations more accurately encompass CGMP. The agency is taking this action based on a request for an extension of the comment period.

DATES: Written comments by September 30, 1996.

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:
Thomas C. Kuchenberg, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1046; or
John M. Dietrick, Center for Drug Evaluation and Research (HFD–325), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–0098; or
William G. Marnane, Center for Veterinary Medicine (HFV–143), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–0678; or
Nancy Roscioli, Center for Biologics Evaluation and Research (HFM–205), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3031.

SUPPLEMENTARY INFORMATION: In the Federal Register of May 3, 1996 (61 FR 20104), FDA published a proposed rule that would clarify certain manufacturing, quality control, and documentation requirements and would ensure that the regulations more accurately encompass CGMP. In addition, the proposed rule would update the requirements for process and methods validation to incorporate guidance previously issued to industry to reflect current practice. The agency proposed these revisions to the CGMP regulations to enhance the integrity of the drug manufacturing process and the safety of drug products. The proposal gave interested persons the opportunity to submit written comments by August 1, 1996.

FDA has received a request from the Nonprescription Drug Manufacturers Association (NDMA) to extend the comment period. NDMA asked that the comment period be extended to permit the nonprescription drug industry to prepare and submit comments to FDA.

FDA has carefully considered this request and has decided to extend the comment period in which interested persons may evaluate the proposed rule and submit comments to the agency. Accordingly, the comment period for submission of comments by any interested person is extended to September 30, 1996.

Interested persons may, on or before September 30, 1996, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one 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 office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 19, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–19158 Filed 7–26–96; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Part 178

[Notice No. 833]

RIN 1512–AB35

Implementation of Public Law 103–322, the Violent Crime Control and Law Enforcement Act of 1994—Importation of Ammunition Feeding Devices With a Capacity of More Than 10 Rounds (94F–022P)

AGENCY: Bureau of Alcohol, Tobacco and Firearms (ATF), Department of the Treasury.

ACTION: Proposed rulemaking cross referenced to temporary regulations.

SUMMARY: In the Rules and Regulations portion of this Federal Register, the Bureau of Alcohol, Tobacco and Firearms (ATF) is issuing temporary regulations which provide that ammunition feeding devices with a capacity of more than 10 rounds manufactured on or before September 13, 1994, the date of enactment of Public Law 103–322, are eligible for importation into the United States for general commercial sale. The temporary rule also provides guidance on acceptable evidence that magazines sought to be imported were manufactured on or before September 13, 1994. The temporary regulations also serve as the text of this notice of proposed rulemaking for final regulations.

DATES: Written comments must be received on or before October 28, 1996.

ADDRESS: Send written comments to: Chief, Regulations Branch; Bureau of Alcohol, Tobacco and Firearms; PO Box 50221; Washington, DC 20091–0221; *ATTN: Notice No.833.*

FOR FURTHER INFORMATION CONTACT: James P. Ficaretta, Regulations Branch, Bureau of Alcohol, Tobacco and Firearms, 650 Massachusetts Avenue, NW., Washington, DC 20226 (202–927–8230).

SUPPLEMENTARY INFORMATION:

Executive Order 12866

It has been determined that this proposed rule is not a significant regulatory action as defined in E.O. 12866, because the economic effects flow directly from the underlying statute and not from this temporary rule. Therefore, a regulatory assessment is not required.