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.

Regulatory Flexibility Act

It is hereby certified that these proposed regulations will not have a significant economic impact on a substantial number of small entities. Accordingly, a regulatory flexibility analysis is not required. The revenue effects of this rulemaking on small businesses flow directly from the underlying statute. Likewise, any secondary or incidental effects, and any reporting, recordkeeping, or other compliance burdens flow directly from the statute.

Paperwork Reduction Act

The collections of information contained in this notice have been submitted to the Office of Management and Budget for review in accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. 3504(h)). Comments on the collections of information should be sent to the Office of Management and Budget, Paperwork Reduction Project 1512–0017, 1512–0018, and 1512–0019, Attention: Desk officer for the Department of the Treasury, Bureau of Alcohol, Tobacco and Firearms, Office of Information and Regulatory Affairs, Washington, DC, 20503, with copies to the Chief, Document Services Branch, Room 3450, Bureau of Alcohol, Tobacco, and Firearms, 650 Massachusetts Avenue, NW., Washington, DC 20226.

The collections of information in this proposed regulation are in 27 CFR 178.119. This information is required by ATF to ensure compliance with the provisions of Pub. L. 103–322 (108 Stat. 1796). The likely respondents are individuals and businesses. Estimated total annual reporting burden: 200 hours. Estimated number of respondents: 2,000. Total annual hours requested: 200.

Public Participation

ATF requests comments on the temporary regulations from all interested persons. Comments received on or before the closing date will be carefully considered. Comments received after that date will be given the same consideration if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before the closing date.

ATF will not recognize any material in comments as confidential. Comments may be disclosed to the public. Any material which the commenter considers to be confidential or inappropriate for disclosure to the public should not be included in the comment. The name of the person submitting a comment is not exempt from disclosure.

Any interested person who desires an opportunity to comment orally at a public hearing should submit his or her request, in writing, to the Director within the 90-day comment period. The Director, however, reserves the right to determine, in light of all circumstances, whether a public hearing is necessary.

The temporary regulations in this issue of the Federal Register amend the regulations in 27 CFR Part 178. For the text of the temporary regulations, see T.D. ATF–383 published in the Rules and Regulations section of this issue of the Federal Register.

Drafting Information: The author of this document is James P. Ficaretta, Regulations Branch, Bureau of Alcohol, Tobacco and Firearms.

Signed: March 18, 1996.

Bradley A. Buckles,

Acting Director.

Approved: June 19, 1996.

John P. Simpson,

Deputy Assistant Secretary (Regulatory, Tariff and Trade Enforcement).

[FR Doc. 96–19190 Filed 7–26–96; 8:45 am]

BILLING CODE 4810–31–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

36 CFR Part 1228

RIN 3095–AA55

Transfer of Electronic Records to the National Archives

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed rule would revise NARA regulations relating to the transfer of permanent electronic records to the National Archives. The proposed rule clarifies the timing of transfers and expands the forms of acceptable transfer media.

DATES: Comments must be received by September 27, 1996.

ADDRESSES: Comments must be sent to Regulation Comment Desk (PIRM-POL), Room 3200, Policy and Planning Division, National Archives and Records Administration, 8601 Adelphi Road, College Park, MD 20740–6001.

FOR FURTHER INFORMATION CONTACT: Nancy Allard at (301) 713–6730, extension 226.

SUPPLEMENTARY INFORMATION: The proposed rule directs agencies to transfer electronic records to the National Archives at the time specified in NARA-approved records schedules or sooner if the agency cannot properly care for the records. The transfer media, formerly limited to open reel magnetic tape or tape cartridges, now includes Compact-Disk, Read Only Memory (CD–ROM) provided that the files contained on the CD–ROM comply with the format and documentation specified in § 1228.188. Open-reel 7-track tape reels recorded at 800 bpi are no longer acceptable. In addition, the proposed section provides more specific transfer information for data files and databases and now includes information for transferring electronic textual documents and digital spatial data files. Finally, agencies are encouraged to transfer documentation in an electronic form.

This proposed rule is not a significant regulatory action for the purposes of Executive Order 12866, and has not been reviewed by OMB. As required by the Regulatory Flexibility Act, it is hereby certified that this proposed rule will not have a significant impact on small entities. This proposed rule is not a major rule as defined in 5 U.S.C. Chapter 8, Congressional Review of Agency Rulemaking.

List of Subjects in 36 CFR Part 1228

Archives and records, Computer technology, Incorporation by reference.

For the reasons set forth in the preamble, NARA proposes to amend part 1228 of title 36, Code of Federal Regulations, as follows:

PART 1228—DISPOSITION OF FEDERAL RECORDS

1. The authority citation for part 1228 continues to read:

Authority: 44 U.S.C. chs. 21, 29, and 33.

2. Section 1228.188 is revised to read as follows:

§ 1228.188 Electronic records.

(a) *Timing of transfers.* Each agency is responsible for the integrity of the records it transfers to the National Archives. To ensure that permanently valuable electronic records are preserved, each Federal agency shall transfer electronic records to the National Archives promptly in accordance with the agency's records disposition schedule. Furthermore, if the agency cannot provide proper care and handling of the media (see part 1234 of this chapter), or if the media are becoming obsolete and the agency cannot migrate the records to newer media, the agency shall contact NARA to arrange for timely transfer of permanently valuable electronic records, even when sooner than provided in the records schedule.