

part 229 of this chapter (Regulation CC), the Uniform Commercial Code, and the Reserve Banks' operating circulars. A paying bank that receives a cash item from a Reserve Bank also may return the item prior to settlement, in accordance with § 210.9(b) of this subpart and the Reserve Banks' operating circulars. The rules or practices of a clearinghouse through which the item was presented, or a special collection agreement under which the item was presented, may not extend these return times, but may provide for a shorter return time.

(2) *Return of checks not handled by Reserve Banks.* A paying bank that receives a check as defined in § 229.2(k) of this chapter (Regulation CC), other than from a Reserve Bank, and that determines not to pay the check, may send the returned check to any Reserve Bank (unless its Administrative Reserve Bank directs it to send the returned check to a specific Reserve Bank) in accordance with subpart C of part 229 of this chapter (Regulation CC), the Uniform Commercial Code, and the Reserve Banks' operating circulars. A returning bank may send a returned check to any Reserve Bank (unless its Administrative Reserve Bank directs it to send the returned check to a specific Reserve Bank) in accordance with subpart C of part 229 of this chapter (Regulation CC), the Uniform Commercial Code, and the Reserve Banks' operating circulars.

(b) *Handling of returned checks.* (1) The following parties, in the following order, are deemed to have handled a returned check sent to a Reserve Bank under paragraph (a) of this section—

- (i) The paying or returning bank;
- (ii) The paying bank's or returning bank's Administrative Reserve Bank;
- (iii) The Reserve Bank that receives the returned check from the paying or returning bank (if different from the paying bank's or returning bank's Administrative Reserve Bank); and
- (iv) Another Reserve Bank, if any, that receives the returned check from a Reserve Bank.

(2) A Reserve Bank that is not described in paragraph (b)(1) of this section is not a party that handles a returned check and is not a returning bank with respect to a returned check.

(3) The identity and order of the parties under paragraph (b)(1) of this section determine the relationships and the rights and liabilities of the parties under this subpart, part 229 of this chapter (Regulation CC), and the Uniform Commercial Code.

(c) *Paying bank's and returning bank's agreement.* * * *

(1) Authorizes the paying or returning bank's Administrative Reserve Bank,

and any other Reserve Bank or returning bank to which the returned check is sent, to handle the returned check (and authorizes any Reserve Bank that handles settlement for the returned check to make accounting entries) subject to this subpart and to the Reserve Banks' operating circulars;

* * * * *

(d) *Warranties by Reserve Bank.* By handling a returned check under this subpart, a Reserve Bank makes the returning bank warranties as set forth in § 229.34 of this chapter, subject to the terms of part 229 of this chapter (Regulation CC). * * *

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(f) *Methods of recovery.* (1) The Reserve Bank may recover the amount stated in paragraph (d) of this section by charging any account on its books that is maintained or used by the paying or returning bank (or by charging another returning Reserve Bank), if—

(i) The Reserve Bank made seasonable written demand on the paying or returning bank to assume defense of the action or proceeding; and

(ii) The paying or returning bank has not made any other arrangement for payment that is acceptable to the Reserve Bank.

(2) The Reserve Bank is not responsible for defending the action or proceeding before using this method of recovery. A Reserve Bank that has been charged under this paragraph (f) may recover from the paying or returning bank in the manner and under the circumstances set forth in this paragraph (f). A Reserve Bank's failure to avail itself of the remedy provided in this paragraph (f) does not prejudice its enforcement in any other manner of the indemnity agreement referred to in paragraph (c)(3) of this section.

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(h) *Settlement.* A subsequent returning bank or depository bank shall settle with its Administrative Reserve Bank for returned checks in the same manner and by the same time as for cash items presented for payment under this subpart. Settlement with its Administrative Reserve Bank is deemed to be settlement with the Reserve Bank from which the returning bank or depository bank received the item.

(i) *Security interest.* When a paying or returning bank sends a returned check to a Reserve Bank, the paying bank, returning bank, and any prior returning bank grant to the paying bank's or returning bank's Administrative Reserve Bank a security interest in all of their respective assets in the possession of, or held for the account of, any Reserve Bank, to secure their respective

obligations due or to become due to the Administrative Reserve Bank under this subpart or subpart C of part 229 of this chapter (Regulation CC). * * *

By order of the Board of Governors of the Federal Reserve System, September 10, 1997.

William W. Wiles,
Secretary of the Board.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 610

Biological Product Standards; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations for biological products standards to update a reference to the United States Pharmacopeia (USP). The agency has determined that the 1995 edition of the USP should be referenced rather than previous editions. This action is necessary to ensure the consistency and accuracy of the regulations.

DATES: The regulation is effective September 15, 1997. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of a certain publication in 21 CFR 610.12(f), effective September 15, 1997.

FOR FURTHER INFORMATION CONTACT: Timothy W. Beth, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301-594-3074.

SUPPLEMENTARY INFORMATION: Section 610.12(f) (21 CFR 610.12(f)) incorporates by reference the 1985 edition of the USP concerning test procedures for membrane filtration. Since the USP has been revised and the 1995 edition of the USP (23d Revision, 1995) is more readily available to the public, FDA has determined that § 610.12(f) should reference the test standards for the "Test Procedures Using Membrane Filtration" in the 1995 edition, in lieu of the test standards in the 1985 edition. The test standards for membrane filtration in the 1995 edition of the USP are identical to

those in the 1985 edition with the following exceptions:

(1) In the second paragraph under "Apparatus," the 1985 edition states "A membrane generally suitable for sterility testing has a normal porosity of .45 +/- 0.02um, * * *," while the 1995 edition does not include the "+/-0.02um"; and

(2) the 1985 edition did not have a section on "Filterable Solids," because information of filterable solids was not available in 1985. The 1995 edition now has this information.

Because these differences in the two editions of the USP are insignificant, and the 1995 edition is more readily available to the public, the agency believes that the regulation should be amended, as indicated herein, to reflect the more recent version of the test standards. Accordingly § 610.12(f) is being amended to reflect the 1995 edition of the USP (23d Revision, 1995).

Publication of this document constitutes final action on this change under the Administrative Procedure Act (5 U.S.C. 553(b)(3)(B)). Notice and public procedure are unnecessary because FDA is merely updating a reference in its regulations.

List of Subjects in 21 CFR Part 610

Biologics, Incorporation by reference, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 610 is amended as follows:

PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

1. The authority citation for 21 CFR part 610 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371); secs. 215, 351, 352, 353, 361 of the Public Health Service Act (42 U.S.C. 216, 262, 263, 263a, 264).

2. Section 610.12 is amended by revising paragraph (f) to read as follows:

§ 610.12 Sterility.

* * * * *

(f) *Membrane filtration.* Bulk and final container material or products containing oil products in water-insoluble ointments may be tested for sterility using the membrane filtration procedure set forth in the United States Pharmacopeia (23d Revision, 1995), section entitled "Test Procedures Using Membrane Filtration," pp. 1689 to 1690, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from

the United States Pharmacopeial Convention, Inc., 12601 Twinbrook Pkwy., Rockville, MD 20852, or available for inspection at the Center for Drug Evaluation and Research's Division of Medical Library, 5600 Fishers Lane, rm. 11B-40, Rockville, MD, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC, except that:

(1) The test samples shall conform with paragraph (d) of this section; and

(2) In addition, for products containing a mercurial preservative, the product shall be tested in a second test using Fluid Thioglycollate Medium incubated at 20 to 25 °C in lieu of the test in Soybean-Casein Digest Medium.

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Dated: September 2, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

RIN 1218-AA95

Methylene Chloride; Amendment; Extension of Start-Up Date

AGENCY: Occupational Safety and Health Administration (OSHA), Department of Labor.

ACTION: Final Rule; amendment; extension of start-up date for compliance.

SUMMARY: The Occupational Safety and Health Administration (OSHA) is extending the start-up date for most provisions of the methylene chloride by 30 days to November 6, 1997 for larger employers. Employers with fewer than 20 employees and foam manufacturers with 20 to 99 employees have substantially later start-up dates which are not changed.

DATES: The effective date of this amendment is September 15, 1997.

Compliance: The start-up date for all provisions of the methylene chloride standard except initial monitoring and engineering controls for employers specified in § 1910.1052(n)(2)(iii)(c) is extended to November 6, 1997 (210 days after the effective date of the standard).

FOR FURTHER INFORMATION CONTACT: Bonnie Freeman, Director, OSHA Office of Public Affairs, U.S. Department of Labor, Room N3647, 200 Constitution

Avenue, NW., Washington, DC 20210, telephone (202) 219-8151.

SUPPLEMENTARY INFORMATION: OSHA published a new methylene chloride standard January 10, 1997 (62 FR 1494). That standard included extended start-up dates for its various provisions depending on the size of the employer. The three categories of employers were employers with fewer than 20 employees, foam manufacturers with 20-99 employees and "all other employers."

OSHA published notification of OMB approval of information collection requirements on August 8, 1997 (62 FR 42666). As the start-up date for initial monitoring for "all other employers" was August 8, 1997, OSHA extended that date to September 7, 1997 to provide added notice to implement compliance.

The next start-up date specified for "all other employers" is October 7, 1997 for all provisions except engineering controls and initial monitoring. That is only 30 days after the extended date for completion of initial monitoring.

OSHA has concluded that more time is needed between completion of initial monitoring and implementation of the other provisions except engineering controls. This allows for a more efficient and effective implementation of those provisions such as for training, medical surveillance and other specified provisions. This is also consistent with OSHA's initial determination that 60 days is needed between completion of initial monitoring and implementation of the other provisions. OSHA is amending § 1910.1052(n)(2)(iii)(c) to implement this decision.

The date for completion of initial monitoring for employers with fewer than 20 employees is February 4, 1998 and for foam manufacturers with 20-99 employees is November 6, 1997. The date for all other provisions except engineering controls is 60 days later for each group. See 62 FR 1606 (January 10, 1997) for a listing of effective and start-up dates.

OSHA finds that there is good cause to issue this extension without notice and public comment because following such procedures would be impractical, unnecessary or contrary to the public interest in this case. OSHA believes that it is in the public interest to give certain employers additional time between completion of initial monitoring and implementation of other provisions.

Authority And Signature

This document was prepared under the direction of Gregory R. Watchman, Acting Assistant Secretary of Labor for Occupational Safety and Health, U.S.