the proposed rule was issued prior to January 1, 1981, and is therefore exempt.

List of Subjects in 21 CFR Part 211

Drugs, Manufacturing, Labeling, Laboratories, Packaging and containers, Warehouses.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 501, 502, 505, 512, 701, 52 Stat. 1049–1053 as amended, 1055–1056 as amended, 82 Stat. 343–351 (21 U.S.C. 351, 352, 355, 360b, 371)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Part 211 is amended by revising § 211.170 to read as follows:

PART 211—CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS

§ 211.170 Reserve samples.

(a) An appropriately identified reserve sample that is representative of each lot in each shipment of each active ingredient shall be retained. The reserve sample consists of at least twice the quantity necessary for all tests required to determine whether the active ingredient meets its established specifications, except for sterility and pyrogen testing. The retention time is as follows:

(1) For an active ingredient in a drug product other than those described in paragraphs (a) (2) and (3) of this section, the reserve sample shall be retained for 1 year after the expiration date of the last lot of the drug product containing the active ingredient.

(2) For an active ingredient in a radioactive drug product, except for nonradioactive reagent kits, the reserve sample shall be retained for:

(i) Three months after the expiration date of the last lot of the drug product containing the active ingredient if the expiration dating period of the drug product is 30 days or less; or

(ii) Six months after the expiration date of the last lot of the drug product containing the active ingredient if the expiration dating period of the drug product is more than 30 days.

(3) For an active ingredient in an OTC drug product that is exempt from bearing an expiration date under § 211.137, the reserve sample shall be retained for 3 years after distribution of the last lot of the drug product containing the active ingredient.

(b) An appropriately identified reserve sample that is representative of each lot or batch of drug product shall be retained and stored under conditions consistent with product labeling. The reserve sample shall be stored in the same immediate container-closure system in which the drug product is marketed or in one that has essentially the same characteristics. The reserve sample consists of at least twice the quantity necessary to perform all the required tests, except those for sterility and pyrogens. Reserve samples, except those drug products described in paragraph (b)(2), shall be examined visually at least once a year for evidence of deterioration unless visual examination would affect the integrity of the reserve samples. Any evidence of reserve sample deterioration shall be investigated in accordance with § 211.192. The results of the examination shall be recorded and maintained with other stability data on the drug product. Reserve samples of compressed medical gases need not be retained. The retention time is as follows:

(1) For a drug product other than those described in paragraphs (b) (2) and (3) of this section, the reserve sample shall be retained for 1 year after the expiration date of the drug product.

(2) For a radioactive drug product, except for nonradioactive reagent kits, the reserve sample shall be retained for:

(i) Three months after the expiration date of the drug product if the expiration dating period of the drug product is 30 days or less; or

(ii) Six months after the expiration date of the drug product if the expiration dating period of the drug product is more than 30 days.

(3) For an OTC drug product that is exempt from bearing an expiration date under § 211.137, the reserve sample must be retained for 3 years after the lot or batch of drug product is distributed.

Effective date: This regulation is effective April 28, 1983.

(Secs. 501, 502, 505, 512, 701, 52 Stat. 1049–1053 as amended, 1055–1056 as amended, 82 Stat. 343–351 (21 U.S.C. 351, 352, 355, 360b, 371))

Dated: February 23, 1983.

Mark Novitch,

Deputy Commissioner of Food and Drugs.

[FR Doc. 83-7935 Filed 3-28-83; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Parts 610, 620, 630, 640, 660, and 680

Biological Products; Editorial Amendments

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending various biologics regulations to correct editorial errors.

EFFECTIVE DATE: March 29, 1983.

FOR FURTHER INFORMATION CONTACT: Albert Rothschild, National Center for Drugs and Biologics (HFN–813), Food and Drug Administration, 8800 Rockville Pike, Rockville, MD 20205, 301–443–1306.

SUPPLEMENTARY INFORMATION: This document corrects several editorial errors in the biologics regulations.

List of Subjects

21 CFR Part 610

Biologics, Labeling.

21 CFR Part 620 and 630

Biologics.

21 CFR Part 640

Blood.

21 CFR Part 660

Biologics, Labeling.

21 CFR Part 680

Biologics, Blood.

Therefore, under the Federal Food, Drugs, and Cosmetic Act (sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a))), and under authority delegated to the Commissioner (21 CFR 5.10), 21 CFR Subchapter F, is amended as follows:

PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

§ 610.15 [Amended]

1. In § 610.15 *Constituent materials*, in the introductory text of paragraph (a), by changing the words "Polio Virus" to read "Poliovirus".

PART 620—ADDITIONAL STANDARDS FOR BACTERIAL PRODUCTS

§ 620.6 [Amended]

2. In § 620.6 *General requirements*, paragraph (h), by changing the name "Bureau of Biologics" to "Office of Biologics".

§ 620.24 [Amended]

3. In § 620.24 *General requirements*, paragraph (c), by changing the name "Bureau of Biologics" to "Office of Biologics".

PART 630—ADDITIONAL STANDARDS FOR VIRAL VACCINES

§ 630.17 [Amended]

4. In § 630.17 *General requirements*, paragraph (e), by changing the name "Bureau of Biologics" to "Office of Biologics".

PART 640—ADDITIONAL STANDARDS FOR HUMAN BLOOD AND BLOOD PRODUCTS

§ 640.30 [Amended]

5. In § 640.30 *Single Donor Plasma (Human)*, paragraph (b)(1), by changing "frm" to "from".

§ 640.34 [Amended]

6. In § 640.34 *Proessing*, paragraph (d) in the third sentence, by changing "cubic milliliter" to microliter".

§ 640.50 [Amended]

7. In § 640.50 *Cryoprecipitated Antihemophilic Factor (Human)*, paragraph (b), by changing "Antihemophili" to Antihemophilic."

§ 640.101 [Amended]

8. In § 640.101 *Red Blood Cells (Human)*, paragraph (f), by changing the name "Bureau of Biologics" to "Office of Biologics".

PART 660—ADDITIONAL STANDARDS FOR DIAGNOSTIC SUBSTANCES FOR LABORATORY TESTS

§ 660.21 [Amended]

9. In § 660.21 *Processing*, paragraph (a)(4), by inserting "lot" after "Each" in the first sentence; in paragraph (f), by changing "Bureau of Biologics" to "Office of Biologics".

§ 660.22 [Amended]

10. In § 660.22 *Reference preparations*, by removing the hyphen over the "e" in "Anti-e".

§ 660.24 [Amended]

11. In § 660.24 *Potency test with reference preparations:*

a. In paragraph (a)(3)(ii) by changing "certifuge" to "centrifuge".

b. In paragraph (b)(1)(ii) by removing the hyphen over the "e" in "Anti-e".

§ 660.25 [Amended]

12. In § 660.25 *Potency test without reference preparations:*

a. In paragraph (a)(5)(i), by placing a hyphen over the "k" in "Anti-k".

b. In paragraph (a)(5)(ii), by placing a hypen over the "s" in "Anti-s", and placing a hyphen over the "c" in "Anti-c"

§ 660.26 [Amended]

13. In § 660.26 *Specificity tests:*

a. In paragraph (b)(1):

(1) by changing "Anti-A^{T2P}" to read "Anti-A", and by changing the corresponding cells to be tested to read "A_1, A_2B, B, O".

(2) By changing "Anti-C" corresponding cells "C+rh_i neg. cells" to read "C+rh_i negative cells".

(3) By changing "Anti-e" to read "Anti-ē".

b. In paragraph (c)(1), by placing a hyphen over "k" and "s", and by removing the hyphen over "e".

§ 660.27 [Amended]

14. In § 660.27 *Aridity test:*

a. In the introductory text of paragraph (b), by changing *"Anti-c"* to read *"Anti-c"*.

b. In paragraph (b)(5), by changing "Anti-ē" to read "Anti-e".

§ 660.28 [Amended]

15. In § 660.28 *Labeling:*

a. In paragraph (a)(1), by changing "Anti-ē" to read "Anti-e".

b. In paragraph (d):

(1) By changing the optional synonym for "Anti-CD" to read "(Anti-RH_o')".

(2) By changing "Anti-ē" to read "Anti-e".

(3) By changing the optional synonym" for "Anti-C^w " to read "Anti-rh^{wi} ".

§ 660.33 [Amended]

16. In § 660.33 *Testing of source material*, in the last sentence by removing the hyphen over "e", and by placing a hyphen over "k" and "s".

§ 660.36 [Amended]

17. In § 660.36 *Samples and protocols*, paragraphs (a) and (b), by changing "Bureau of Biologics" to "Office of Biologics".

PART 680—ADDITIONAL STANDARDS FOR MISCELLANEOUS PRODUCTS

§ 680.21 [Amended]

18. In § 680.21 *Reference preparations*, by changing "Bureau of Biologics" to "Office of Biologics" and by changing the zip code "20014" to "20205".

§ 680.24 [Amended]

19. In § 680.24 *General requirements*, paragraph (e), by changing "Bureau of Biologics" to "Office of Biologics".

§ 680.26 [Amended]

20. In § 680.26 *Samples; protocols; official release*, in the introductory text by changing "Bureau of Biologics" to "Office of Biologics" and by changing the zip code "20014" to "20205" and in paragraph (c) by changing "Bureau of biologics" to "Office of Biologics."

Effective date. March 29, 1983.

(Sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a)))

Dated: March 18, 1983.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 83-7940 Filed 3-28-83; 8:45 a.m.]

BILLING CODE 4160-01-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[Docket No. RI-693; A-1-FRL 2305-4]

Approval and Promulgation of Implementation Plans; Rhode Island; Energy Initiative

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is approving State Implementation Plan revisions submitted by the State of Rhode Island. These provisions provide temporary variances from sulfur-in-fuel and particulate emission limitations for small fuel burning sources which commit to convert to a fuel other than oil, to establish permanent energy conservation measures, or to bubble allowable emissions. The intended effect of this action is to provide cost-effective energy alternatives to Rhode Island sources with only a minimal increase in emissions, while assuring no violations of the National Ambient Air Quality Standards (NAAQS).

EFFECTIVE DATE: March 29, 1983.

ADDRESSES: Copies of the submittal are available for public inspection at Room 2111, JFK Federal Building, Boston, MA 02203; Public Information Reference Unit, EPA Library, 401 M Street, SW., Washington, D.C. 20460; Office of the Federal Register, 1100 L Street, NW., Room 8401, Washington, D.C. 20408 and the Division of Air and Hazardous Materials, Room 204, 75 Davis Street, Providence, RI 02908.

FOR FURTHER INFORMATION CONTACT: Betsy Horne, (617) 223-5130.

SUPPLEMENTARY INFORMATION: On January 4, 1983 (48 FR 274), EPA published a Notice of Proposed Rulemaking (NPR) for revisions to Rhode Island's Regulation 8, "Sulfur Content of Fuels," and Regulation 13, "Particulate Emissions from Fossil Fuel Fired Steam or Hot Water Generating Units." These amendments allow small fuel burning sources (less than 250 million Btu per hour) temporary variances from sulfur-in-fuel and particulate emission limitations in order to effect energy conservation or conversion measures or to bubble emissions to achieve a cost-effective control strategy. The requirements and conditions of the regulations being approved today and EPA's reasons for approving these revisions were discussed in the NPR. Since no public comment was received on that action,

EPA's reasons for the approval will not be repeated here.

Action

EPA is approving revisions to Regulations 8 and 13 submitted on November 9, 1982.

EPA finds good cause for making this action effective immediately because the implementation plan revisions are already in effect under State law and the EPA approval imposes no additional regulatory burdens.

In the NPR, EPA proposed approval of all individual sources which are later determined to meet the eligibility requirements of the new regulations and set forth the procedures by which EPA will conduct its proposed rulemaking process for individual sources concurrent with the State's review process. Therefore, this notice does not give final approval to individual sources which meet the eligibility requirements of the new regulation. Before final approval, these sources must be processed in accordance with the concurrent State/EPA procedures set forth in the NPR. Individual SIP revisions for each eligible source will be submitted to EPA by Rhode Island at some future date at which time EPA will proceed to final rulemaking for these individual sources.

EPA specifically solicited comments in the NPR on this new parallel, concurrent State/EPA processing of individual sources since it is a departure from EPA's usual procedure of conducting a separate, proposed rulemaking only after the State has completed its review and determination for each source requesting a relaxation of the sulfur-in-fuel limitation. No comments were received concerning this new approach. EPA believes that this new approach is a significant regulatory reform which will substantially reduce the time required to complete the SIP revision process for these sources.

The Office of Management and Budget has exempted this rule from the requirements of Section 3 of Executive Order 12291.

Under section 307(b)(1) of the Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by (60 days from today).

This action may not be challenged later in proceedings to enforce its requirements (see sec. 307(b)(2)).

List of Subjects in 40 CFR Part 52

Air pollution control, Ozone, Sulfur oxides, Nitrogen dioxide, Lead, Particulate matter, Carbon monoxide, and Hydrocarbons.

(Secs. 110(a) and 301(a) of the Clean Air Act, as amended (42 U.S.C. 7410(a) and 7601(a)))

Note.—Incorporation by reference of the State Implementation Plan for the State of Rhode Island was approved by the Director of the Federal Register on July 1, 1982.

Dated: March 21, 1983.

John W. Hernandez,

Acting Administrator.

PART 52—[AMENDED]

Part 52 of Chapter I, Title 40 of the Code of Federal Regulations is amended as follows:

Subpart 00—Rhode Island

1. Section 52.2070 is amended by adding paragraph (c)(17) as follows:

§ 52.2070 Identification of plan.

* * * * *

(c)* * *

(17) Revisions to Regulations 8, "Sulfur Content of Fuels" and 13, "Particulate Emissions from Fossil Fuel Fired Steam or Hot Water Generating Units" were submitted on November 9, 1982 by the Division of Air and Hazardous Materials.

[FR Doc. 83-8060 Filed 3-28-83; 8:45 am]

BILLING CODE 6560-50-M

40 CFR Parts 123 and 262

Hazardous Waste Management System; State Program Requirements: Standards Applicable to Generators of Hazardous Waste; International Shipments

AGENCY: Environmental Protection Agency (EPA).

ACTION: Technical Amendments.

SUMMARY: In regulations promulgated on February 26, 1980 and May 19, 1980, EPA established standards for generators of hazardous waste. Included in the standards were requirements for the international shipment of hazardous waste. In this action, EPA amends the international shipment requirements to make a minor technical correction. The Agency is today correcting the address to which the export notice must be sent.

EFFECTIVE DATE: March 29, 1983.

FOR FURTHER INFORMATION CONTACT: RCRA Hotline toll-free at (800) 424-9346 or at (202) 382-3000. Debra Wolpe 382-2222.

SUPPLEMENTARY INFORMATION:

Background

EPA has established standards for managing hazardous waste, in regulations under the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act of 1976, as amended (RCRA), 42 U.S.C. 6901 *et seq.* These standards include certain requirements for generators of hazardous waste who intend to export this waste outside the jurisdiction of the United States, 40 CFR 262.50 (45 FR 12734, February 26, 1980, republished with amendments, 45 FR 33144, May 19, 1980).

Generally these standards require that a generator notify EPA four weeks before exporting a shipment of hazardous waste. EPA then sends the information contained in the generator's notice to the State Department, which in turn forwards it to the government of the receiving country. The purpose of the notice is to ensure that hazardous waste is exported only with the knowledge of the receiving country so that the country can evaluate the significance of the export.

40 CFR 262.50 and 123.34 incorrectly state the address to which the international shipment notices must be sent. The Agency is therefore amending both these sections to reflect the correct address: Office of International Activities (A-106), U.S. Environmental Protection Agency, Washington, D.C. 20460.

The regulations provide that the notice must be sent to EPA Headquarters, not EPA Regional Offices or States authorized under 40 CFR Part 123. EPA Regional Offices are not in a position to notify the Department of State or foreign countries. Thus, all generators must notify the EPA Administrator at the address given above.

Dated: March 21, 1983.

Lee M. Thomas,

Acting Associate Administrator for Solid Waste and Emergency Response.

Parts 262 and 123 of Title 40 of the Code of Federal Regulations are amended as follows:

PART 262—[AMENDED]

1. The authority citation for Part 262 reads as follows:

Authority: Sections 1006, 2002, 3002, 3003, 3004, and 3005, Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act of 1976, as amended (RCRA) (42 U.S.C. 6905, 6912, 6922, 6923, 6924, 6925).

2. 40 CFR 262.50 is amended by correcting paragraph (b)(1)(iii) to read as follows:

§ 262.50 International shipments.

* * * * *

(b) * * *

(1) * * *

(iii) These notices must be sent to the Office of International Activities (A–106), United States Environmental Protection Agency, Washington, D.C. 20460.

* * * * *

PART 123—[AMENDED]

3. The authority citation for Part 123 reads as follows:

Authority: Resource Conservation and Recovery Act, 42 U.S.C. 6901 et seq.; Safe Drinking Water Act, 42 U.S.C. 300(f) et seq.; Clean Water Act, 33 U.S.C. 1251 et seq.; unless otherwise noted.

4. 40 CFR 123.34 is amended by correcting the note after paragraph (e) as follows:

§ 123.34 Requirements for generators of hazardous wastes.

* * * * *

(e) * * *

Note.—Such notices shall be mailed to the Office of International Activities (A–106), United States Environmental Protection Agency, Washington, D.C. 20460.

* * * * *

[FR Doc. 83-7857 Filed 3-28-83; 8:45 am]

BILLING CODE 6560-50-M

GENERAL SERVICES ADMINISTRATION

41 CFR Ch. 101

[FPMR Temp. Reg. A-22, Supp. 1]

Use of Contract Airline Service Between Selected City-Pairs

AGENCY: Office of Federal Supply and Services, GSA.

ACTION: Temporary regulations.

SUMMARY: This regulation amends FPMR Temporary Regulation A–22 to provide that airline contract services and fares apply not only to Government employees but also to their dependents who are authorized to travel at Government expense. The contract provision that includes dependents was inadvertently omitted from the original regulation. In addition, this regulation cancels a requirement for Federal agencies to report to the General Services Administration (GSA) certain information pertaining to the use of scheduled airlines by employees and military personnel and their dependents on official travel between city-pairs listed in Federal Travel Directory. GSA has determined that the purposes for which these reports were required can be achieved through other sources.

DATES:

Effective date: March 29, 1983.

Expiration date: September 30, 1983

FOR FURTHER INFORMATION CONTACT: Joseph M. Napoli, Policy Development and Analysis Division (703–557–1256).

SUPPLEMENTARY INFORMATION: GSA has determined that this rule is not a major rule for the purposes of Executive Order 12291 of February 17, 1981, because it is not likely to result in an annual effect on the economy of $100 million or more, a major increase in costs to consumers or on others, or significant adverse effects. GSA has based all administrative decisions underlying this rule on adequate information concerning the need for, and consequences of, this rule; has determined that the potential benefits to society from this rule outweigh the potential costs and has maximized the net benefits; and has chosen the alternative approach involving the least net cost to society.

(Sec. 205(c), 63 Stat. 390; 40 U.S.C. 486(c))

In 41 CFR Chapter 101, the following regulation is added to the appendix at the end of Subchapter A to read as follows:

Ray Kline,

Acting Administrator of General Services.

March 8, 1983.

Federal Property Management Regulations Temporary Regulation A–22, Supplement 1

March 8, 1983.

To: Heads of Federal agencies

Subject: Use of contract airline service between selected city-pairs

1. *Purpose.* This supplement amends the scope of FPMR Temporary Regulation A–22, October 30, 1982 (47 FR 53373, November 26, 1982), set forth in paragraph 5, to include dependents authorized to travel at Government expense. In addition, this supplement cancels the reporting requirement set forth in paragraph 13.

2. *Effective date.* This regulation is effective March 29, 1983.

3. *Expiration date.* This supplement expires September 30, 1983, unless sooner superseded or canceled.

4. *Explanation of changes.*

a. The introductory sentence in paragraph 5 is revised to read as follows: "The extent to which this regulation applies to Government employees and military personnel and their dependents authorized to travel at Government expense is as follows:". The balance of paragraph 5 remains unchanged.

b. Paragraph 13 of FPMR Temporary Regulation A–2 requires Federal agencies to submit three reports in the format illustrated in attachment A of the regulation. The reporting requirement has been assigned interagency report control number 0242–GSA–XX. The General Services Administration has developed alternate methods to obtain the required data in a manner that will provide sufficient information to evaluate the usage of the city-pair contracts by Federal agencies. Accordingly, the reporting requirement is canceled.

5. *Action.* Make the following changes in FPMR Temporary Regulation A–22:

a. Revise the introductory sentence in paragraph 5 to read as shown in 4a, above; and

b. Delete paragraph 13 and attachment A and label them "reserved".

Ray Kline,

Acting Administrator of General Services.

[FR Doc. 83-8007 Filed 3-28-83; 8:45 am]

BILLING CODE 6820-AM-M

41 CFR Ch. 101

[FPMR Temp. Reg. E-76, Supp. 1]

Acquisition of Systems Furniture

AGENCY: Office of Federal Supply and Services, GSA.

ACTION: Temporary regulation.

SUMMARY: This supplement extends to February 29, 1984, the expiration date of FPMR Temporary Regulation E–76.

DATES:

Effective date: March 1, 1983.

Expiration date: February 29, 1984.

FOR FURTHER INFORMATION CONTACT: Dan Rowan, Furniture Commodity Center (703–557–8473).

SUPPLEMENTARY INFORMATION: The General Services Administration has determined that this rule is not a major rule for the purposes of Executive Order 12291 of February 17, 1981, because it is not likely to result in an annual effect on the economy of $100 million or more; a major increase in costs to consumers or others; or significant adverse effects. The General Services Administration has based all administrative decisions underlying this rule on adequate information concerning the need for, and consequences of, this rule; has determined that the potential benefits to society from this rule outweigh the potential costs and has maximized the net benefits; and has chosen the alternative approach involving the least net cost to society.

(Sec. 205(c), 63 Stat. 390; 40 U.S.C. 486(c))

In 41 CFR Chapter 101, this temporary regulation is listed in the appendix at the end of Subchapter E.

Ray Kline,

Acting Administrator of General Services.

Federal Property Management Regulations Temporary Regulation E–76 Supplement 1

March 7, 1983.

To: Heads of Federal agencies

Subject: Acquisition of systems furniture

1. *Purpose.* This supplement extends the expiration date of FPMR Temporary Regulation E–76.

2. *Effective date.* March 1, 1983.