in furtherance of the purposes of the Act.

(d) *Contents of notice required by paragraph (c)(1).* Any notice filed pursuant to paragraph (c)(1) of this section, shall consist of the following, as appropriate:

* * * * *

VI. Statutory Basis

The proposed amendments to Rule 19d–1 are adopted under the Securities Exchange Act of 1934, 15 U.S.C. 78f, 78k–1, 78*o*, 78*o*–3, 78q, 78q–1, 78s and 78w.

Dated: June 1, 1984.

By the Commission.

George A. Fitzsimmons,

Secretary.

[FR Doc. 84–15461 Filed 6–7–84; 8:45 am]

BILLING CODE 8010–01–M

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 101

[T.D. 84–39]

Customs Regulations Amendment Relating to the Customs Field Organization—Bridgeport, Connecticut

AGENCY: Customs Service, Treasury.

ACTION: Final rule; Suspension of Effective Date.

SUMMARY: This document suspends until September 30, 1984, the effective date of a document which amended the Customs Regulations relating to the field organization of the Customs Service. In order to complete administrative adjustments, it has been determined necessary to suspend the effective date of changing the status of the Bridgeport, Connecticut, Customs district by placing it under the Boston, Massachusetts, Customs district. The document was published in the **Federal Register** on Friday, February 10, 1984 (49 FR 5092; FR Doc. 84–3707).

EFFECTIVE DATE: June 8, 1984.

FOR FURTHER INFORMATION CONTACT: Renee De Atley, Office of Inspection and Control, U.S. Customs Service, 1301 Constitution Avenue, NW., Washington, D.C. 20229, (202–566–8157).

The amendments to 19 CFR Part 101 published in the **Federal Register** on Friday, February 10, 1984 (49 FR 5092; FR Doc. 84–3707) are suspended until September 30, 1984.

Dated: June 4, 1984.

Robert P. Schaffer,

Assistant Commissioner (Commercial Operations).

[FR Doc. 84–15306 Filed 6–7–84; 8:45 am]

BILLING CODE 4820–02–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 73, 74, 103, 105, 131, 133, 135, 136, 137, 139, 145, 146, 150, 155, 160, 161, 163, 164, 166, 168, and 169

[Docket No. 84N–0025]

Incorporation by Reference; Updating of Text; Confirmation of Effective Date

AGENCY: Food and Drug Administration.

ACTION: Final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date of the final rule that updated the incorporations by reference found in various sections of FDA's regulations. That action was taken to meet the requirements for incorporation by reference set forth in Title 1 of the Code of Federal Regulations (1 CFR Part 51).

DATE: Effective date confirmed: April 19, 1984.

FOR FURTHER INFORMATION CONTACT: Michael E. Kashtock, Center for Food Safety and Applied Nutrition (formerly Bureau of Foods) (HFF–334), Food and Drug Administration, 200 C St. SW., Washington, D.C. 20204, 202–472–5690.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 30, 1984 (49 FR 3804), FDA published a proposal to amend certain of its regulations to update existing incorporations by reference to meet the requirements for incorporation by reference set forth in 1 CFR Part 51. That provision requires the filing and updating of material that has been incorporated by reference in the Code of Federal Regulations. The purpose of this requirement is to ensure the public availability and accuracy of material that has been incorporated from other sources. The agency received two comments in response to the January 30, 1984 proposal and published a final rule in the **Federal Register** of March 19, 1984 (49 FR 10087).

Any person adversely affected by the regulations was given an opportunity to file written objections to the final regulations and to request a hearing on those objections on or before April 18, 1984. No objections or requests for a hearing were received.

List of Subjects

21 CFR Part 73

Color additives, Cosmetics, Drugs, Incorporation by reference, Medical devices.

21 CFR Part 74

Color additives, Cosmetics, Drugs, Incorporation by reference; Medical devices.

21 CFR Part 103

Incorporation by reference, Quality standards.

21 CFR Part 105

Dietary foods, Food labeling, Incorporation by reference, Infant foods, Nutrition, Vitamins and minerals.

21 CFR Part 131

Cream, Food standards, Incorporation by reference, Milk, Yogurt.

21 CFR Part 133

Cheese, Food standards, Incorporation by reference.

21 CFR Part 135

Food standards, Frozen desserts, Ice cream, Incorporation by reference.

21 CFR Part 136

Bakery products, Bread, Food standards, Incorporation by reference.

21 CFR Part 137

Cereals, Flour, Food standards, Incorporation by reference.

21 CFR Part 139

Food standards, Incorporation by reference, Macaroni, Noodles.

21 CFR Part 145

Canned fruit, Food standards, Fruit, Incorporation by reference.

21 CFR Part 146

Canned fruit juice, Food standards, Fruit juices, Incorporation by reference.

21 CFR Part 150

Food standards, Fruit butter, Incorporation by reference, Jam, Jelly.

21 CFR Part 155

Canned vegetables, Food standards, Incorporation by reference, Vegetables.

21 CFR Part 160

Eggs, Food Standards, Incorporation by reference.

21 CFR Part 161

Fish, Food standards, Incorporation by reference, Seafood.

21 CFR Part 163

Cacao products, Chocolate, Food standards, Incorporation by reference.

21 CFR Part 164

Food standards, Incorporation by reference, Nuts, Peanuts.

21 CFR Part 166

Food standards, Incorporation by reference, Margarine.

21 CFR Part 168

Food standards, Incorporation by reference, Sirups, Sugars.

21 CFR Part 169

Food dressings, Food standards, Incorporation by reference, Vanilla.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 701(e), 706, 72 Stat. 1784–1788 as amended, 74 Stat. 399–407 as amended (21 U.S.C. 371(e), 376)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), notice is given that no objections or requests for hearing were filed in response to the March 19, 1984 final rule. Accordingly, the amendments promulgated thereby became effective on April 19, 1984.

Dated: June 1, 1984.

William V. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 84-15349 Filed 6-7-84; 8:45 am]

BILLING CODE 4160-01-M

---

21 CFR Parts 600, 601, 606, 607, 610, 620, 630, 640, 650, 660, and 680

Biological Products; Update of Organizational References

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its biologics regulations following a reorganization to update organizational references and clarify delegations of authority regarding biological products.

EFFECTIVE DATE: June 8, 1984.

FOR FURTHER INFORMATION CONTACT: Michael L. Hooton, Center for Drugs and Biologics (formerly National Center for Drugs and Biologics) (HFN–368), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1306.

SUPPLEMENTARY INFORMATION: In the Federal Register of March 19, 1984 (49 FR 10168), FDA announced a reorganization of FDA's Center for Drugs and Biologics to abolish three existing line offices and establish five new line offices that combine similar drugs and biologics functions. To implement that reorganization and update its regulations for biological products, FDA is amending 21 CFR Parts 600 through 680. The agency essentially is delegating authority to take actions on biological products to the Office of Biologics Research and Review (HFN–800), Center for Drugs and Biologics.

Because these amendments relate to agency management and personnel and are not substantive, the rule is exempt from the notice and comment and delayed effective date requirements of section 553 (b) and (d)(3) of the Administrative Procedure Act (5 U.S.C. 553 (b) and (d)(3)).

This rule has no economic impact. Hence, in accordance with section 605(b) of the Regulatory Flexibility Act, FDA certifies that the rule will not have a significant economic impact on a substantial number of small entities. The rule is related to agency organization, management, and personnel and therefore is exempt from Executive Order 12291.

List of Subjects in 21 CFR Parts 600, 601, 606, 607, 610, 620, 630, 640, 650, 660, and 680

Biologics, Blood, Labeling, Laboratories.

Therefore, under the Public Health Service Act (sec. 351, 58 Stat. 702 as amended (42 U.S.C. 262)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), 21 CFR Subchapter F is amended in Parts 600 through 680 as follows:

PART 600—BIOLOGICAL PRODUCTS: GENERAL

1. The words " 'Bureau of Biologics' means 'Bureau of Biologics of' " are changed to read " 'Office of Biologics Research and Review' means 'Office of Biologics Research and Review, Center for Drugs and Biologics of' " in § 600.3(d); the words "Bureau of Biologics" are changed to read "Center for Drugs and Biologics" in § 600.10; the words "Bureau of Biologics" are changed to read "Office of Biologics Research and Review" wherever they appear in §§ 600.11, 600.12, 600.13, 600.15, and 600.22; and the words "Bureau Biologics" are changed to read "Office of Compliance, Center for Drugs and Biologics (HFN–355), 5600 Fishers Lane, Rockville, MD 20857" in § 600.14.

PART 601—LICENSING

2. The words "Bureau Biologics" are changed to read "Office of Biologics Research and Review" and the words "Bureau of Drugs" are changed to read "Office of Drug Research and Review" wherever they appear in § 601.2; the words "Commissioner of Food and Drugs" are changed to read "Director, Office of Biologics Research and Review" wherever they appear in §§ 601.3 and 601.4(a); the reference "§ 601.6 and" is changed to read "§ 601.6 or" in the next to the last sentence in § 601.5(b); the words "Bureua of Biologics" are changed to read "Office of Biologics Research and Review" in § 601.6(a); the word "Commissioner" is changed to read "Director, Office of Biologics Research and Review" in § 601.9(a); the words "Bureau of Biologics" are changed to read "Office of Biologics Research and Review" wherever they appear in §§ 601.12, 601.31, 601.33 and 601.51.

PART 606—CURRENT GOOD MANUFACTURING PRACTICES FOR BLOOD AND BLOOD COMPONENTS

3. The words "Bureau of Biologics" are changed to read "Center for Drugs and Biologics" in § 606.20; the words "Bureau of Biologics" are changed to read "Office of Biologics Research and Review" wherever they appear in §§ 606.100 and 606.110; and the words "Bureau of Biologics" are changed to read "Office of Compliance, Center for Drugs and Biologics" wherever they appear in § 606.170.

PART 607—ESTABLISHMENT REGISTRATION AND PRODUCT LISTING FOR MANUFACTURERS OF HUMAN BLOOD AND BLOOD PRODUCTS

4. The words "Bureau of Biologics (HFB–14), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20205" are changed to read "Office of Compliance, Center for Drugs and Biologics (HFN–315), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857" wherever they appear in §§ 607.7, 607.22, and 607.37; the words "Bureau of Biologics" are changed to read "Office of Biologics Research and Review" in § 607.25; and paragraph (b) in § 607.35 is removed and paragraphs (c) and (d) are redesignated as paragraphs (b) and (c), respectively.

PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

5. The words "Bureau of Biologics" are changed to read "Office of Biologics

Research and Review" and the words "Bureau of Drugs" are changed to read "Office of Drug Research and Review" wherever they appear in §§ 610.2, 610.11, 610.12 (also the words "National Center for Drugs and Biologics" are changed to read "Office of Biologics Research and Review" in § 610.12), 610.15, 610.20, 610.40 (also the words "Office of Biologics (HFN–800), National Center for Drugs and Biologics" are changed to read "Office of Biologics Research and Review (HFN–800)" in § 610.40), and 610.53.

PART 620—ADDITIONAL STANDARDS FOR BACTERIAL PRODUCTS

6. The words "Office of Biologics" and "Bureau of Biologics" are changed to read "Office of Biologics Research and Review" and the words "Commissioner of Food and Drugs" are changed to "Director, Office of Biologics Research and Review" wherever they appear in §§ 620.6, 620.12, 620.13, 620.14, 620.21, 620.22, 620.24, 620.31, 620.32, 620.35, 620.43, 620.44, 620.45, and 620.48.

PART 630—ADDITIONAL STANDARDS FOR VIRAL VACCINES

7. The words "Commissioner of Food and Drugs" are changed to read "Director, Office of Biologics Research and Review" and the words "Bureau of Biologics" or "Office of Biologics" are changed to read "Office of Biologics Research and Review" wherever they appear in §§ 630.1, 630.2, 630.3, 630.4, 630.5, 630.10, 630.12, 630.13, 630.14, 630.17, 630.30, 630.33, 630.36, 630.50, 630.53, 630.56, 630.60, 630.63, 630.66, 630.70, 630.72, 630.74, 630.75, 630.81, 630.83, and 630.86.

PART 640—ADDITIONAL STANDARDS FOR HUMAN BLOOD AND BLOOD PRODUCTS

8. The words "Commissioner of Food and Drugs" are changed to read "Director, Office of Biologics Research and Review" and the words "Bureau of Biologics" are changed to read "Office of Biologics Research and Review" wherever they appear in §§ 640.2, 640.3, 640.4, 640.6, 640.17, 640.21, 640.22, 640.25, 640.55, 640.56, 640.64, 640.66, 640.71, 640.73, 640.74, 640.75, 640.82, 640.92, 640.101, 640.104, 640.111, and 640.112.

PART 650—ADDITIONAL STANDARDS FOR DIAGNOSTIC SUBSTANCES FOR DERMAL TESTS

9. The words "Bureau of Biologics" are changed to read "Office of Biologics Research and Review" and the words "Commissioner of Food and Drugs" are changed to read "Director, Office of Biologics Research and Review" wherever they appear in §§ 650.6 and 650.11.

PART 660—ADDITIONAL STANDARDS FOR DIAGNOSTIC SUBSTANCES FOR LABORATORY TESTS

10. The words "Bureau of Biologics" and "Office of Biologics" are changed to read "Office of Biologics Research and Review" wherever they appear in §§ 660.3, 660.5, 660.6, 660.21, 660.22, 660.23, 660.26, 660.28, 660.29, 660.32, 660.36, 660.42, 660.44, 660.46, 660.101, 660.102, 660.103, and 660.105.

PART 680—ADDITIONAL STANDARDS FOR MISCELLANEOUS PRODUCTS

11. The words "Bureau of Biologics" and "Office of Biologics" are changed to read "Office of Biologics Research and Review" wherever they appear in §§ 680.4, 680.11, 680.12, 680.21, 680.24, and 680.26.

Effective date. June 8, 1984.

(Sec. 351, 58 Stat. 702 as amended (42 U.S.C. 262))

Dated: June 1, 1984.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 84-15350 Filed 6-7-84; 8:45 am]

BILLING CODE 4160-01-M

---

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs Not Subject to Certification; Prednisolone Sodium Phosphate Injection, Sterile; Removal of Regulation

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is revoking that portion of the animal drug regulations reflecting approval of a new animal drug application (NADA) providing for intravenous use of prednisolone sodium phosphate injection for treating horses and dogs when an adrenal glucocorticoid and/or anti-inflammatory effect is required. The sponsor, Burns-Biotec Laboratories, Inc., requested the withdrawal of approval.

EFFECTIVE DATE: June 18, 1984.

FOR FURTHER INFORMATION CONTACT: David N. Scarr, Center for Veterinary Medicine (formerly Bureau of Veterinary Medicine) (HFV–214), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1846.

SUPPLEMENTARY INFORMATION: In a notice published elsewhere in this issue of the **Federal Register**, approval of NADA 97–566 which provides for use in horses and dogs of Burns-Biotec Laboratories' Cortisate-10 (prednisolone sodium phosphate) Injection is withdrawn. This document amends the animal drug regulations to revoke that portion of 21 CFR 522.1883 which reflects approval of the NADA.

List of Subjects in 21 CFR Part 522

Animal drugs, Injectable.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

§ 522.1883 [Amended]

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(e), 82 Stat. 345–347 (21 U.S.C. 360b(e))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Veterinary Medicine (21 CFR 5.84), Part 522 is amended in § 522.1883 *Prednisolone sodium phosphate injection, sterile* by removing paragraph (b) and marking it "Reserved."

Effective date: June 18, 1984.

(Sec. 512(e), 82 Stat. 345–347 (21 U.S.C. 360b(e)))

Dated: June 4, 1984.

Lester M. Crawford,

Director, Center for Veterinary Medicine.

[FR Doc. 84-15346 Filed 6-7-84; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 916

Approval of Permanent Program Amendment From the State of Kansas Under the Surface Mining Control and Reclamation Act of 1977

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Final rule.

SUMMARY: OSM is announcing the approval of a program amendment submitted by Kansas as an amendment to the State's permanent regulatory program (hereinafter referred to as the Kansas program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA)).