

*abortus* not to exceed 15 herds per 1,000 (1.5 percent). Prior to the effective date of this document the entire State of Arkansas was classified as a Class B State. A review of Arkansas brucellosis program records for the 12-month period June 1, 1982, through May 31, 1983, indicates that the adjusted MCI rate for that period is 0.408 percent. Also, records establish that the herd infection rate for the same 12 month period exceeds 1.5 percent. Under these circumstances, Arkansas no longer meets the requirements for Class B status.

A State or area is required to be given Class C status if it falls below the requirements for Class B but maintains certain minimal procedural standards, including standards concerning testing, tracing, and conducting epidemiologic investigations. It appears that Arkansas meets the criteria for Class C status.

The regulations at § 78.1(v) provide that prior to lowering the classification of a State or Area, the Deputy Administrator for Veterinary Service shall provide the affected State notice an opportunity to be heard. The regulations at § 78.25(a) also provide that prior to lowering the classification of a State or Area, the State animal health official of the State involved will be notified of such downgrading, and shall be given an opportunity to request an administrative review and to present objections and arguments to the Deputy Administrator prior to the downgrading taking effect. These requirements were met.

Under the circumstances referred to above, it is necessary to reclassify Arkansas from Class B to Class C.

#### Executive Order and Regulatory Flexibility Act

This rule is issued in conformance with Executive Order 12291 and Secretary's Memorandum No. 1512-1, and has been determined to be not a "major rule." Based on information compiled by the Department, it has been determined that this rule will not have a significant effect on the economy; will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and will not cause adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

There are approximately 2 million head of cattle in Arkansas distributed among approximately 51,000 herds. The herds range in size from several head to

over a thousand head. For purposes of action under the Regulatory Flexibility Act, most of the cattle producers in Arkansas are considered to be small entities.

Changing the status of Arkansas from Class B to Class C imposes additional testing requirements on the interstate movement of certain cattle. Records concerning the movement, testing, and slaughter of cattle indicate that most of the cattle sold at markets in Arkansas remain in Arkansas. Cattle moved interstate from Arkansas are moved for slaughter, for use as breeding stock, or for feeding. Under the regulations, cattle moved interstate for immediate slaughter, or to quarantined feedlots will not be subject to the additional testing requirements. Also, calfhood vaccinates and cattle from Certified Brucellosis-free herds moving interstate are not subject to the additional testing under the regulations.

Although this amendment is extremely significant for helping to prevent the interstate spread of brucellosis, the number of cattle moved interstate from Arkansas which will be affected by this amendment is insignificant compared to the number of cattle moved interstate within the United States.

Under these circumstances, Mr. Bert W. Hawkins, Administrator of the Animal and Plant Health Inspection Service, has determined that this action will not have a significant economic impact on a substantial number of small entities.

#### Emergency Action

Dr. John K. Atweel, Deputy Administrator of the Animal and Plant Health Inspection Service for Veterinary Services has determined that an emergency situation exists which warrants publication of this interim rule without prior opportunity for public comment. Immediate action is necessary to prevent the interstate spread of brucellosis.

Further, pursuant to the administrative procedure provisions in 5 U.S.C. 533, it is found upon good cause that notice and other public procedures with respect to this interim rule are impracticable and contrary to the public interest and good cause is found for making this interim rule effective less than 30 days after publication of this document in the *Federal Register*. Comments have been solicited for 60 days after publication of this document. A final document discussing comments received and any amendments required will be published in the *Federal Register* as soon as possible.

#### List of Subjects in 9 CFR Part 78

Animal diseases, Cattle, Quarantine, Transportation, Brucellosis.

#### PART 78—BRUCELLOSIS

##### § 78.20 [Amended]

Accordingly, the Brucellosis regulations in 9 CFR Part 78 are amended by removing "Arkansas," in § 78.20(c) and by adding "Arkansas," immediately before "Florida" in § 78.20(d).

[Secs. 4, 5, 6, 23 Stat. 32, as amended; secs. 1 and 2, 32 Stat. 791-792, as amended; sec. 3, 33 Stat. 1265, as amended; sec. 2, 65 Stat. 693; and secs. 3 and 11, 76 Stat. 130, 132, (21 U.S.C. 111-113, 114a-1, 115, 120, 121, 125, 134b, 134f); 7 CFR 2.17, 2.51, and 371.2 (d)]

Done at Washington, D.C., this 29th day of July, 1983.

J. K. Atweel,

Deputy Administrator, Veterinary Services.

[FR Doc. 83-20947 Filed 7-29-83; 12:16 pm]

BILLING CODE 3410-34-M

#### FEDERAL RESERVE SYSTEM

##### 12 CFR Part 220

#### Credit by Brokers and Dealers; Technical Amendments to Revision and Simplification of Regulation T

**AGENCY:** Board of Governors the Federal Reserve System.

**ACTION:** Final Rule; Technical Amendments.

**SUMMARY:** The Board is making technical amendments to its final rule on Regulation T (Credit by Brokers and Dealers) published at 48 FR 23161, May 24, 1983. This action is necessary to include language in sections 2 (Definitions) and 17 of the regulation (Requirements for List of OTC Margin Stocks) that was inadvertently omitted or was the result of typographical errors. The language to be included reflects the Board's May 12, 1982 revision of criteria for initial and continued inclusion on the List of OTC margin stocks published at 47 FR 21756, May 20, 1982.

**EFFECTIVE DATE:** November 21, 1983 or any earlier date after June 20, 1983, at the option of the creditor.

**FOR FURTHER INFORMATION CONTACT:** Jamie Lenoci, Financial Analyst, or Douglas Blass, Attorney, Division of Banking Supervision and Regulation, Board of Governors of the Federal Reserve System, Washington, D.C. 20551. (202) 452-2781.

**SUPPLEMENTARY INFORMATION:** The last sentence of § 220.2(s) of the final rule in 12 CFR 220 (48 FR 23161,

23166, May 24, 1983) is corrected to read as follows:

(s) \* \* \* An OTC stock is not considered to be an "OTC margin stock" unless it appears on the Board's periodically published list of OTC margin stocks.

Section 17(a)(3) of the final rule in 12 CFR 220 (48 FR 23161, 23171, May 24, 1983) is corrected to read as follows:

(3) The stock is registered under section 12 of the Act, is issued by an insurance company subject to section 12(g)(2)(G) of the Act, is issued by a closed-end investment management company subject to registration pursuant to section 8 of the Investment Company Act of 1940 (15 U.S.C. 80a-8), is an American Depository Receipt (ADR) of a foreign issuer whose securities are registered under section 12 of the Act, or is a stock of an issuer required to file reports under section 15(d) of the Act;

#### § 220.17 [corrected]

Section 220.17(a)(9) of the final rule in 12 CFR 220 (48 FR 23161, 23171, May 24, 1983) is corrected to read as follows:

(a) \* \* \*

(9) The issuer or a predecessor in interest has been in existence for at least three years.

Board of Governors of the Federal Reserve System, July 27, 1983.

William W. Wiles,

Secretary of the Board.

[FR Doc. 83-20780 Filed 8-1-83; 8:45 am]

BILLING CODE 6210-01-M

## FEDERAL DEPOSIT INSURANCE CORPORATION

### 12 CFR Part 303

Applications, Requests, Submittals, Delegations of Authority, and Notices of Acquisition of Control Forms, Instructions, and Reports, Foreign Activities of Insured State Nonmember Banks

#### Correction

In FR Doc. 83-16463 beginning on page 28073 in the issue of Monday, June 20, 1983, makes the following correction:

On page 28076, middle column, § 303.2 (a), twelve lines from the bottom of the page, "published not more" should have read "published or not more".

BILLING CODE 1505-01-M

## COMMODITY FUTURES TRADING COMMISSION

### 17 CFR Part 140

#### Delegation of Authority To Determine Whether an Application for Contract Market Designation is Materially Incomplete

**AGENCY:** Commodity Futures Trading Commission.

**ACTION:** Final rule.

**SUMMARY:** The Commission is amending Part 140 of its rules by adding a provision delegating authority to certain Commission officials to determine whether applications for contract market designations are materially incomplete. The recent amendment to Section 6 of the Commodity Exchange Act by Section 218 of the Futures Trading Act of 1982, Pub. L. 97-444, 96 Stat. 2308 provides for a one year period during which the Commission shall consider applications for contract market designations. The running of this one year period can be stayed by the Commission when the application for designation is materially incomplete. The Commission has determined to delegate to the Directors of the Divisions which analyze such applications its authority to determine whether such applications are materially incomplete. The Commission's action relates solely to agency organization, procedure and practice.

**EFFECTIVE DATE:** August 2, 1983.

**FOR FURTHER INFORMATION CONTACT:** Paul M. Architzel, Chief Counsel, Division of Economics and Education, Commodity Futures Trading Commission 2033 K Street, NW., Washington, D.C. 20581, telephone (202) 254-6990.

**SUPPLEMENTARY INFORMATION:** The Futures Trading Act of 1982 ("1982 Act"), Pub. L. 97-444, 96 Stat. 2294, became effective on January 11, 1983. The 1982 Act amended Section 6 of the Commodity Exchange Act to provide that the Commission must consider applications for contract market designation within one year of the submission of the application. The Commission can stay the running of that period, however, if the application is materially incomplete. To eliminate the necessity for the Commission itself to consider the relative completeness of each designation application when filed, the Commission is amending Part 140 of its rules by adding § 140.75, which delegates to certain Commission officials the authority to determine

whether contract market applications are materially incomplete as filed.<sup>1</sup>

The Commission is delegating to the Directors of the Divisions of Economics and Education and Trading and Markets, and their designees, the authority to make the determination and to notify any contract market that its application is materially incomplete. The Commission anticipates that contract market applications will be deemed to be materially incomplete if they fail to address any of the criteria for contract market designation applications identified in Commission Guideline No. 1, 47 FR 49838 (November 3, 1982), to be codified at 17 CFR Part 5, Appendix A, or any other applicable requirements for contract market designation. Applications which fail to provide sufficiently detailed analysis of the specific criteria required to be addressed, or which fail to provide sufficient data supporting such analyses, will also be deemed to be materially incomplete. In addition, applications will be deemed to be materially incomplete if proposed exchange rules which are necessary to implement or meet the various criteria for contract market designation are absent.

The Commission has determined that this amendment to Part 140 relates solely to agency organization, procedure, and practice. Therefore, the provisions of the Administrative Procedure Act, 5 U.S.C. 553, which generally require notice of proposed rulemaking and which provide other opportunities for public participation, are not applicable.<sup>2</sup> The Commission further finds that, because of the need promptly to update this rule in light of the enactment of the Futures Trading Act of 1982, there is good cause to make this amendment effective immediately upon publication in the Federal Register.

#### List of Subjects in 17 CFR Part 140

Contract market designation, Contract markets, Application for contract market designation.

#### PART 140—[AMENDED]

In consideration of the foregoing, and pursuant to the authority contained in the Commodity Exchange Act and in particular, Sections 2(a)(11), and 6 of the Act, 7 U.S.C. 4a(j) and 8, as amended by the Futures Trading Act of 1982 Pub. L.

<sup>1</sup> To the extent that Section 6 of the Act is applicable to the designation of contract markets in options under Commission Rule 33.2, 17 CFR 33.2 (1982), this delegation of Section 6 authority is also applicable.

<sup>2</sup> Similarly, the provisions of the Regulatory Flexibility Act, Pub. L. 96-354, 94 Stat. 1164, do not apply. See 5 U.S.C. 601(2).

97-444, 96 Stat. 2294; 2308 (1983), the Commission hereby amends Chapter 1 of Title 17 of the Code of Federal Regulations as follows:

Part 140 is amended by adding § 140.77 to read as follows:

**§ 140.77 Delegation of authority to determine that applications for contract market designation are materially incomplete.**

(a) The Commodity Futures Trading Commission hereby delegates, until such time as the Commission orders otherwise, to the Directors of the Division of Economics and Education and the Division of Trading and Markets or their designees, the authority to determine that an application for contract market designation is materially incomplete under Section 6 of the Commodity Exchange Act and to so notify the applicant.

(b) The Directors of the Division of Economics and Education and the Division of Trading and Markets may submit any matter which has been delegated to them under paragraph (a) of this section to the Commission for its consideration.

(c) Nothing in this section may prohibit the Commission, at its election, from exercising the authority delegated to the Directors of the Division of Economics and Education and the Division of Trading and Markets under paragraph (a) of this section.

Issued in Washington, District of Columbia on July 26, 1983, by the Commission.

Jane K. Stuckey,

Secretary to the Commission.

[FR Doc. 83-20726 Filed 8-1-83; 8:45 am]

BILLING CODE 6351-01-M

**DELAWARE RIVER BASIN COMMISSION**

**18 CFR Part 410**

**Amendment of Basin Regulations; Water Code and Water Quality Standards**

**AGENCY:** Delaware River Basin Commission.

**ACTION:** Final rule; correction.

**SUMMARY:** This document corrects the amendatory language pertaining to a Part heading on Basin Regulations published July 21, 1983 (48 FR 33258).

**FOR FURTHER INFORMATION CONTACT:** Susan M. Weisman, Commission Secretary, Delaware River Basin Commission; P.O. Box 7360, West Trenton, New Jersey 08628; Telephone (609) 883-9500.

**SUPPLEMENTARY INFORMATION:**

Accordingly, on page 33256, column 3, lines 5 and 6 are corrected to read as follows: "410 is revised to read as follows:"

(Delaware River Basin Compact, 75 Stat. 688)

Susan M. Weisman,

Secretary.

July 26, 1983.

[FR Doc. 83-20702 Filed 8-1-83; 8:45 am]

BILLING CODE 6360-01-M

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 74**

[Docket No. 83C-01380]

**[Phthalocyaninato(2-)] Copper; Listing as a Color Additive for Coloring Contact Lenses**

**AGENCY:** Food and Drug Administration.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the color additive regulations to provide for the safe use of [phthalocyaninato(2-)] copper as a color additive for coloring contact lenses. This action responds to a petition filed by Wilsa, Inc. FDA is also incorporating the listing of this color additive for use in sutures into the subpart of its regulations that the agency recently established for medical devices.

**DATES:** Effective September 2, 1983; objections by September 1, 1983.

**ADDRESS:** Written objections may be sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:**

Geraldine E. Harris, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

**SUPPLEMENTARY INFORMATION:** In a notice published in the Federal Register of May 17, 1983 (48 FR 22212), FDA announced that a color additive petition (CAP 3C0166) had been filed by Wilsa, Inc., P.O. Box 36142, Denver, CO 80236, proposing that the color additive regulations be amended to provide for the safe use of [phthalocyaninato(2-)] copper for coloring contact lenses. The petition was filed under section 706 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 376).

With the passage of the Medical Device Amendments of 1976 (Pub. L. 94-295), Congress mandated the listing of color additives for use in medical

devices where the color additive comes in direct contact with the body for a significant period of time (section 706(a) of the act). The use of [phthalocyaninato(2-)] copper presented in the petition before the agency is subject to this listing requirement. The color additive is added to contact lenses in such a way that at least some of the color additive will come in contact with the eye when the lenses are worn. In addition, the lenses are intended to be placed on the eye for several hours each day for 1 year or more. Thus, the color additive will come in direct contact with the body for a significant period of time.

The agency, having evaluated the data in the petition and other relevant material, finds that [phthalocyaninato(2-)] copper is safe and suitable for use in coloring contact lenses under the conditions prescribed in new § 75.3045 (21 CFR 74.3045). FDA has established a limitation of 0.01 percent by weight for [phthalocyaninato(2-)] copper in contact lenses because this is the level requested by the petitioner and because the available ocular study does not support the safety of the use of this color additive at higher levels.

FDA previously listed this color additive (CAS Reg. No. 147-14-8 (an editorial addition)) for use in polypropylene sutures used in general and ophthalmic surgery under § 74.1045 (21 CFR 74.1045). Sutures, which were regulated as drugs before the passage of the Medical Device Amendments of 1976, are now regulated as medical devices. Recently, in a regulation published in the Federal Register of March 29, 1983 (48 FR 13020), FDA amended the color additive regulations by establishing a Subpart D under 21 CFR Part 74. To avoid redundancy and to simplify the regulations pertaining to this color additive, the agency is removing § 74.1045 and incorporating the provisions of that section in new § 74.3045 in Subpart D. The agency has revised the restriction that had appeared in § 74.1045(c), that the color additive regulation does not waive the requirements of section 505 of the act with respect to the drug in which the color additive is used, to reflect the status of sutures as medical devices. Thus, § 74.3045(c)(3) states that the medical devices in which this color additive is used (including sutures) are subject to the requirements of sections 510(k), 515, and 520(g) of the act instead of section 505.

In accordance with § 71.15 (21 CFR 71.15), the color additive petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for

inspection at the Bureau of Foods by appointment with the information contact person listed above. As provided in § 71.15(b), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has considered the potential environmental effects of this action and has concluded that this action will not have a significant impact on the human environment and that an environmental impact statement therefore will not be prepared. The agency's finding of no significant impact may be seen in the Dockets Management Branch (address above), between 9 a.m. and 4 p.m., Monday through Friday.

#### List of Subjects in 21 CFR Part 74

Color additives, Color additives subject to certification; Cosmetics, Drugs, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 701(e), 706, 70 Stat. 919 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), Part 74 is amended as follows:

#### PART 74—LISTING OF COLOR ADDITIVES SUBJECT TO CERTIFICATION

##### § 74.1045 [Removed]

- By removing § 74.1045 [*Phthalocyaninato(2-)*] copper.
- By adding new § 74.3045 to Subpart D, to read as follows:

##### § 74.3045 [*Phthalocyaninato(2-)*] copper.

(a) *Identity.* The color additive is [*phthalocyaninato(2-)*] copper (CAS Reg. No. 147-14-8) having the structure shown in Colour Index No. 74160.

(b) *Specifications.* The color additive [*phthalocyaninato(2-)*] copper shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by current good manufacturing practice:

Volatile matter 135° C (275° F), not more than 0.3 percent.

Salt content (as NaCl), not more than 0.3 percent.

Alcohol soluble matter, not more than 0.5 percent.

Organic chlorine, not more than 0.2 percent.

Aromatic amines, not more than 0.05 percent.

Lead (as Pb), not more than 40 parts per million.

Arsenic (as As), not more than 3 parts per million.

Mercury (as Hg), not more than 1 part per million.

Total color, not less than 98.5 percent.

(c) *Uses and restrictions.* (1) The color additive [*phthalocyaninato(2-)*] copper may be safely used to color polypropylene sutures for use in general and ophthalmic surgery subject to the following restrictions:

(i) The quantity of the color additive does not exceed 0.5 percent by weight of the suture.

(ii) The dyed suture shall conform in all respects to the requirements of the United States Pharmacopeia.

(iii) When the sutures are used for the purposes specified in their labeling, there is no migration of the color additive to the surrounding tissue.

(2) The color additive [*phthalocyaninato(2-)*] copper may be safely used for coloring contact lenses when incorporated in the lens at levels not to exceed 0.01 percent by weight of the lens material.

(3) Authorization for these uses shall not be construed as waiving any of the requirements of section 510(k), 515, or 520(g) the Federal Food, Drug, and Cosmetic Act with respect to the medical device in which [*phthalocyaninato(2-)*] copper is used.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of [*phthalocyaninato(2-)*] copper shall be certified in accordance with regulations in Part 80 of this chapter.

Any person who will be adversely affected by the foregoing regulation may at any time, on or before September 1, 1983, file with the Dockets Management Branch (address above) written objections thereto. Objections shall show how the person filing will be adversely affected by the regulation, specify with particularity the provisions of the regulation deemed objectionable, and state the grounds for the objection. Objections shall be filed in accordance with the requirements of 21 CFR 71.30. If a hearing is requested, the objections shall state the issues for the hearing and shall be supported by grounds factually and legally sufficient to justify the relief sought, and shall include a detailed description and analysis of the factual information intended to be presented in support of the objections in the event that a hearing is held. Three copies of all documents shall be filed and shall be identified with the docket number found in brackets in the heading of this

document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

*Effective date.* This regulation shall become effective September 2, 1983, except as to any provisions that may be stayed by the filing of proper objections. Notice of the filing of objections or lack thereof will be announced by publication in the Federal Register.

(Secs. 701(e), 706, 70 Stat. 919 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 371(e), 376))

Dated: July 21, 1983.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 83-20798 Filed 8-1-83; 8:45 am]

BILLING CODE 4180-01-M

#### 21 CFR Part 436

#### Antibiotic Drugs; Cefazolin Sodium Injection

##### Correction

In FR Doc. 83-19535, beginning on page 33478, in the issue of Friday, July 22, 1983, make the following correction.

On page 33479, first column, § 436.342(f), the first equation should have read:

$$\text{Micrograms of cefazolin per milligram} = \frac{R_n \times P_n \times X_{100}}{R_n \times C_n \times (100 - m)}$$

#### 21 CFR Part 522

#### Implantation or Injectable Dosage Form New Animal Drugs Not Subject To Certification; Lactic Acid

AGENCY: Food and Drug Administration.

ACTION: Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Philips Roxane, Inc., providing for use of lactic acid to castrate bull calves.

**EFFECTIVE DATE:** August 2, 1983.

**FOR FURTHER INFORMATION CONTACT:** Adriano R. Gabuten, Bureau of Veterinary Medicine (HFV-135), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4913.