

Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

#### List of Subjects in 21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended to read as follows:

#### PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

**Authority:** 21 U.S.C. 360b.

#### § 520.2043 [Amended]

2. Section 520.2043 *Pyrantel pamoate suspension* is amended in paragraph (b)(2) by removing “Nos. 000069 and 011615” and adding in its place “Nos. 000069, 011615, and 059130”.

Dated: August 20, 1998.

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*

[FR Doc. 98–23107 Filed 8–27–98; 8:45 am]

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### Food and Drug Administration

#### 21 CFR Part 522

#### Implantation or Injectable Dosage Form New Animal Drugs; Progesterone and Estradiol Benzoate

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Fort Dodge Animal Health. The supplemental NADA provides for reimplantation of steers fed in confinement for slaughter with a progesterone-estradiol implant 70 days following an initial implant of a lower dose implant.

**EFFECTIVE DATE:** August 28, 1998.

**FOR FURTHER INFORMATION CONTACT:** Jack Caldwell, Center For Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0217.

**SUPPLEMENTARY INFORMATION:** Fort Dodge Animal Health, Division of American Home Products Corp., 800 Fifth St., NW., P.O. Box 518, Fort Dodge, IA 50501, filed supplemental NADA 9–576 that provides for use of Synovex® S (200 milligrams (mg) progesterone and 20 mg estradiol benzoate) implanted in the ear of steers fed in confinement for slaughter at approximately day 70 following initial implant of Synovex® C (100 mg progesterone and 10 mg estradiol benzoate) when used as part of a reimplant program for increased rate of weight gain. The supplemental NADA is approved as of July 14, 1998, and the regulations in 21 CFR 522.1940 are amended by adding paragraph (d)(3) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

#### List of Subjects in 21 CFR Part 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

#### PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

**Authority:** 21 U.S.C. 360b.

2. Section 522.1940 is amended by adding paragraph (d)(3) to read as follows:

#### § 522.1940 Progesterone and estradiol benzoate in combination.

\* \* \* \* \*

(d) \* \* \*

(3) *Steers fed in confinement for slaughter*—(i) *Amount.* Reimplant 200 milligrams of progesterone and 20 milligrams of estradiol benzoate on approximately day 70 following an initial implant of 100 milligrams of progesterone and 10 milligrams of estradiol benzoate or 200 milligrams of progesterone and 20 milligrams of estradiol benzoate.

(ii) *Indications for use.* For additional improvement in rate of weight gain.

(iii) *Limitations.* For subcutaneous ear implantation.

Dated: August 18, 1998.

**Andrew J. Beaulieu,**

*Acting Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.*

[FR Doc. 98–23109 Filed 8–27–98; 8:45 am]

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#### DEPARTMENT OF THE TREASURY

#### Fiscal Service

#### 31 CFR Part 359

#### Offering Regulations for United States Savings Bonds, Series I

**AGENCY:** Bureau of the Public Debt, Fiscal Service, Treasury.

**ACTION:** Final rule.

**SUMMARY:** The Department of the Treasury (“Department” or “Treasury”) is publishing in final form an amendment to the offering circular for United States Series I savings bonds. The amendment is a technical change to accommodate the first Series I savings bond offering, effective September 1, 1998.

**EFFECTIVE DATE:** September 1, 1998.

**ADDRESSES:** Copies of this final rule are available for downloading from the Bureau of the Public Debt at the following World Wide Web address: <<http://www.savingsbonds.gov>> or may be obtained from the Bureau of the Public Debt, Division of Staff Services, 200 3rd St., Parkersburg, WV 26106–1328.

**FOR FURTHER INFORMATION CONTACT:** Wallace L. Earnest, Director, Division of Staff Services, at (304) 480–6319 or by e-mail at <[wearnest@bpd.treas.gov](mailto:wearnest@bpd.treas.gov)>; Edward C. Gronseth, Deputy Chief Counsel, at (304) 480–5192 or by e-mail at <[egronset@bpd.treas.gov](mailto:egronset@bpd.treas.gov)>; or Dean A. Adams, Assistant Chief Counsel, Office of the Chief Counsel, at (304) 480–5192 or by e-mail at <[dadams@bpd.treas.gov](mailto:dadams@bpd.treas.gov)>.

**SUPPLEMENTARY INFORMATION:** 31 CFR Part 359, referred to as the offering circular, sets out the terms and conditions for the sale and issuance of United States savings bonds, Series I, by the Department of the Treasury to the public. The Department is issuing in final form an amendment to the offering circular as a technical change to accommodate the first Series I savings bond offering, effective September 1, 1998. The offering regulations currently provide that the Series I composite rate will be set forth in rate announcements published each May and November. The composite rate consists of the fixed rate of return and the variable semiannual inflation rate for inflation-indexed savings bonds. The initial rate announcement, effective September 1, 1998, will reflect the Secretary's determination of the fixed rate of return for bonds during the two-month period beginning September 1, 1998, through October 31, 1998. The variable semiannual inflation rate will reflect the rate of change in the CPI-U for the six-month period ending with March 31, 1998.

#### Procedural Requirements

This final rule does not meet the criteria for a "significant regulatory action" pursuant to Executive Order 12866. Therefore, the regulatory review procedures contained therein do not apply.

This final rule relates to matters of public contract and procedures for U.S. securities. The notice and public procedures requirements of the Administrative Procedure Act are inapplicable, pursuant to 5 U.S.C. 553 (a)(2).

Since no notice of proposed rulemaking is required, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601, *et seq.*) do not apply.

There is no new collection of information contained in this final rule, and, therefore, the Paperwork Reduction Act (44 U.S.C. 3507) does not apply.

#### List of Subjects in 31 CFR Part 359

Bonds, Federal Reserve System, Government securities, Securities.

Dated: August 24, 1998.

**Donald V. Hammond,**

*Acting Fiscal Assistant Secretary.*

For the reasons set forth in the preamble, 31 CFR Chapter II, Subchapter B, is amended as follows:

#### PART 359—OFFERING OF UNITED STATES SAVINGS BONDS, SERIES I

1. The authority citation for part 359 continues to read as follows:

**Authority:** 5 U.S.C. 301; 12 U.S.C. 391; 31 U.S.C. 3105.

2. In § 359.2, paragraphs (e)(1)(i) through (e)(1)(v) are revised to read as follows:

#### § 359.2 Description of bonds.

\* \* \* \* \*

(e) *Composite rates and redemption values.* (1) The following definitions apply for determining the composite rates and redemption values:

(i) *Rate announcements.* Rates applicable to Series I bonds will be furnished in rate announcements published each May 1 and November 1, or at any other date determined by the Secretary or the Secretary's designee. If the regularly scheduled date for the announcement (for example, May 1) is a day when the Treasury is not open for business, then the announcement is made on the next business day; however, the effective date of the rates remains the first day of the month of the announcement.

(ii) *Fixed rate of return.* Each May and November, or at any other date determined by the Secretary or the Secretary's designee, the Secretary shall establish the fixed rate of return for Series I bonds issue-dated during the six-month period, or any other period determined by the Secretary or the Secretary's designee, beginning on such date. Such fixed rate of return will be applicable for the life of the bond.

(iii) *Semiannual inflation rate.* Each May and November, or at any other date determined by the Secretary or the Secretary's designee, Treasury will announce a variable semiannual inflation rate for Series I bonds. The index used to determine this rate will be the non-seasonally adjusted U.S. City Average All Items Consumer Price Index for All Urban Consumers ("CPI-U") published by the Bureau of Labor Statistics ("BLS") of the U.S.

Department of Labor. The semiannual inflation rate to be effective with the May announcement, and the rate that is effective for Series I bonds offered from September 1, 1998, through October 31, 1998, will reflect the rate of change in the CPI-U for the six-month period ending with the immediately preceding March 31. The rate of change over the six-month period will be expressed as a percentage, rounded to the nearest one-hundredth of one percent. More specifically, the semiannual inflation rate will reflect the CPI-U value for the most recent March less the value for the preceding September, that difference will then be divided by the CPI-U value for the preceding September, and the result will be multiplied by 100 to convert the rate to a percentage. The

resulting rate will be rounded to the nearest one-hundredth of one percent. The semiannual inflation rate to be effective with the November announcement, reflecting the change in the CPI-U for the six-month period ending with the immediately preceding September, will be similarly determined. In certain deflationary conditions, the semiannual inflation rate may be negative to such an extent that it will offset the fixed rate of return. However, the redemption value of a Series I bond for any particular month will not be less than the value for the preceding month. (See § 359.3(b) for a discussion of the lag between when inflation is measured and when it is reflected in the value of a bond.)

(iv) *Index contingencies.* If a previously reported CPI-U is revised, Treasury will continue to use the previously reported CPI-U in calculating redemption values. If the CPI-U is rebased to a different year, Treasury will continue to use the CPI-U based on the base reference period in effect when the security was first issued, as long as that CPI continues to be published. If, while an inflation-indexed savings bond is outstanding, the applicable CPI-U is: discontinued, in the judgment of the Secretary, fundamentally altered in a manner materially adverse to the interests of an investor in the security, or in the judgment of the Secretary, altered by legislation or Executive Order in a manner materially adverse to the interests of an investor in the security, Treasury, after consulting with the Bureau of Labor Statistics ("BLS"), or any successor agency, will substitute an appropriate alternative index. Treasury will then notify the public of the substitute index and how it will be applied. Determinations of the Secretary in this regard will be final.

(v) *Composite rate.* (A) The fixed rate of return, FR, and the semiannual inflation rate, SIR, as determined in paragraphs (e)(1)(ii) and (iii) of this section are divided by 100 to remove the percentage format (*i.e.*, to convert to decimal form) and are then combined into a composite annual rate, CR, in accordance with the following formula:  

$$CR = \{SIR + (FR \div 2) + [SIR \times (FR \div 2)]\} \times 2$$

(B) The resulting annual rate is converted to a percentage and is rounded to the nearest one-hundredth of one percent. The composite rates will be announced by Treasury each May and November, or at any other date determined by the Secretary or the Secretary's designee, and will be derived from the semiannual inflation

rate announced on the same date and the fixed rates of return applicable to Series I savings bonds.

\* \* \* \* \*

3. In § 359.3, paragraph (b)(1) is revised to read as follows:

**§ 359.3 Investment considerations.**

\* \* \* \* \*

(b) *Inflation lag.* (1) The inflation rate component of investor earnings will be determined twice each year. This rate will be the percentage change in the CPI-U for the six months ending each March and September. The rate will be included in the composite rate that is announced each May and November. For Series I bonds offered from September 1, 1998, through October 31, 1998, the inflation rate component of investor earnings will be the percentage change in the CPI-U for the six months ending March 31, 1998. This rate will be included in the composite rate that is announced for Series I bonds offered effective from September 1, 1998, through October 31, 1998. In the event the Secretary, or the Secretary's designee, announces a composite rate at an effective date other than May 1 or November 1, the announcement will specify the period to be used to calculate the semiannual inflation rate. Each composite rate will be effective for the entirety of the applicable rate period that begins while the rate is in effect. Thus, an inflation rate may affect interest accruals from 3 to 13 months from the date that the CPI-U is measured.

\* \* \* \* \*

[FR Doc. 98-23145 Filed 8-25-98; 4:00 pm]

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## DEPARTMENT OF TRANSPORTATION

### Coast Guard

#### 33 CFR Part 165

[CGD01-98-123]

RIN 2115-AA97

#### Safety Zone: Connections Unlimited Fireworks, New York Harbor, Upper Bay

**AGENCY:** Coast Guard, DOT.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary safety zone for the Connections Unlimited fireworks program located in Federal Anchorage 20C, New York Harbor, Upper Bay. This action is necessary to provide for the safety of life on navigable waters during the event. This action is intended to

restrict vessel traffic in a portion of Federal Anchorage 20C.

**DATES:** This rule is effective from 11 p.m. on Saturday, September 19, 1998, until 12:30 a.m. on Sunday, September 20, 1998.

**ADDRESSES:** Documents as indicated in this preamble are available for inspection or copying at Coast Guard Activities New York, 212 Coast Guard Drive, room 205, Staten Island, New York 10305, between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays. The telephone number is (718) 354-4195.

**FOR FURTHER INFORMATION CONTACT:** Lieutenant (Junior Grade) A. Kenneally, Waterways Oversight Branch, Coast Guard Activities New York, at (718) 354-4195.

**SUPPLEMENTARY INFORMATION:**

**Regulatory History**

Pursuant to 5 U.S.C. 553, a notice of proposed rulemaking (NPRM) was not published for this regulation. Good cause exists for not publishing an NPRM and for making this regulation effective less than 30 days after **Federal Register** publication. Due to the date this application was received, there was insufficient time to draft and publish an NPRM. Any delay encountered in this regulation's effective date would be contrary to public interest since immediate action is needed to close a portion of the waterway and protect the maritime public from the hazards associated with this fireworks display.

**Background and Purpose**

On August 3, 1998, Bay Fireworks submitted an Application for Approval of Marine Event to hold a fireworks program on the waters of Upper New York Bay in Federal Anchorage 20C. The fireworks program is being sponsored by Connections Unlimited. This regulation establishes a safety zone in all waters of Upper New York Bay within a 300 yard radius of the fireworks barge located in approximate position 40°41'24.5"N 074°02'25"W (NAD 1983), approximately 300 yards northeast of Liberty Island, New York. The safety zone is in effect from 11 p.m. on Saturday, September 19, 1998, until 12:30 a.m. on Sunday, September 20, 1998. There is no rain date for this event. The safety zone prevents vessels from transiting a portion of Federal Anchorage 20C and is needed to protect boaters from the hazards associated with fireworks launched from a barge in the area. Recreational and commercial vessel traffic will be able to anchor in the unaffected northern and southern portions of Federal Anchorage 20C.

Federal Anchorages 20A and 20B, to the north, and Federal Anchorages 20D and 20E, to the south, are also available for vessel use. There will be no impact on vessels transiting the shipping channel as the safety zone does not extend into it. Public notifications will be made prior to the event via the Local Notice to Mariners and marine information broadcasts.

**Regulatory Evaluation**

This final rule is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. It has not been reviewed by the Office of Management and Budget under the Order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979). The Coast Guard expects the economic impact of this final rule to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary. This finding is based on the limited marine traffic in the area, the minimal time that vessels will be restricted from the zone, that vessels may safely anchor to the north and south of the zone, and extensive advance notifications which will be made.

**Small Entities**

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Coast Guard considered whether this rule will have a significant economic impact on a substantial number of small entities. "Small entities" include small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

For reasons discussed in the Regulatory Evaluation above, the Coast Guard certifies under section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) that this final rule will not have a significant economic impact on a substantial number of small entities.

**Collection of Information**

This final rule does not provide for a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

**Federalism**

The Coast Guard has analyzed this final rule under the principles and criteria contained in Executive Order 12612 and has determined that this final rule does not have sufficient