

**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 Pfizer, Inc. The NADA provides for the veterinary prescription use of gonadotropin releasing factor-diphtheria toxoid conjugate by subcutaneous injection for temporary immunological castration (suppression of testicular function) and reduction of boar taint in intact male pigs intended for slaughter.

**DATES:** This rule is effective May 13, 2011.

**FOR FURTHER INFORMATION CONTACT:**

Matthew Lucia, Center for Veterinary Medicine (HFV-128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8116, e-mail: [matthew.lucia@fda.hhs.gov](mailto:matthew.lucia@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Pfizer, Inc., 235 East 42d St., New York, NY 10017-5755, filed NADA 141-322 that provides for the veterinary prescription use of IMPROVEST (gonadotropin releasing factor-diphtheria toxoid conjugate) Sterile Solution for Injection for temporary immunological castration (suppression of testicular function) and reduction of boar taint in intact male pigs intended for slaughter. The application is approved as of March 22, 2011, and the regulations are amended in 21 CFR part 522 to reflect approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 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 Division of Dockets Management (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.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning on the date of approval.

The Agency has determined under 21 CFR 25.33 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.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

**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. Add § 522.1083 to read as follows:

**§ 522.1083 Gonadotropin releasing factor-diphtheria toxoid conjugate.**

(a) *Specifications.* Each milliliter (mL) of solution contains 0.2 milligrams (mg) gonadotropin releasing factor-diphtheria toxoid conjugate.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use in swine—(1) Amount.* Administer 0.4 mg per intact male pig (2 mL) by subcutaneous injection no earlier than 9 weeks of age. A second subcutaneous injection of 0.4 mg per intact male pig (2 mL) should be administered at least 4 weeks after the first dose. Pigs should be slaughtered no earlier than 4 weeks and no later than 8 weeks after the second dose.

(2) *Indications for use.* For the temporary immunological castration (suppression of testicular function) and reduction of boar taint in intact male pigs intended for slaughter.

(3) *Limitations.* Not approved for use in female pigs and barrows. Do not use in intact male pigs intended for breeding because of the disruption of reproductive function. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: May 4, 2011.

**Bernadette Dunham,**

*Director, Center for Veterinary Medicine.*

[FR Doc. 2011-11762 Filed 5-12-11; 8:45 am]

**BILLING CODE 4160-01-P**

**PENSION BENEFIT GUARANTY CORPORATION**

**29 CFR Part 4022**

**Benefits Payable in Terminated Single-Employer Plans; Interest Assumptions for Paying Benefits**

**AGENCY:** Pension Benefit Guaranty Corporation.

**ACTION:** Final rule.

**SUMMARY:** This final rule amends the Pension Benefit Guaranty Corporation's regulation on Benefits Payable in Terminated Single-Employer Plans to prescribe interest assumptions under the regulation for valuation dates in June 2011. The interest assumptions are used for paying benefits under terminating single-employer plans covered by the pension insurance system administered by PBGC.

**DATES:** Effective June 1, 2011.

**FOR FURTHER INFORMATION CONTACT:**

Catherine B. Klion, Manager, Regulatory and Policy Division, Legislative and Regulatory Department, Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005, 202-326-4024. (TTY/TDD users may call the Federal relay service toll-free at 1-800-877-8339 and ask to be connected to 202-326-4024.)

**SUPPLEMENTARY INFORMATION:** PBGC's regulation on Benefits Payable in Terminated Single-Employer Plans (29 CFR part 4022) prescribes actuarial assumptions—including interest assumptions—for paying plan benefits under terminating single-employer plans covered by title IV of the Employee Retirement Income Security Act of 1974. The interest assumptions in the regulation are also published on PBGC's Web site (<http://www.pbgc.gov>).

PBGC uses the interest assumptions in Appendix B to Part 4022 to determine whether a benefit is payable as a lump sum and to determine the amount to pay. Appendix C to Part 4022 contains interest assumptions for private-sector pension practitioners to refer to if they wish to use lump-sum interest rates determined using PBGC's historical methodology. Currently, the rates in Appendices B and C of the benefit payment regulation are the same.

The interest assumptions are intended to reflect current conditions in the financial and annuity markets. Assumptions under the benefit payments regulation are updated monthly. This final rule updates the benefit payments interest assumptions for June 2011.<sup>1</sup>

The June 2011 interest assumptions under the benefit payments regulation will be 2.50 percent for the period during which a benefit is in pay status and 4.00 percent during any years preceding the benefit's placement in pay status. In comparison with the interest

<sup>1</sup> Appendix B to PBGC's regulation on Allocation of Assets in Single-Employer Plans (29 CFR Part 4044) prescribes interest assumptions for valuing benefits under terminating covered single-employer plans for purposes of allocation of assets under ERISA section 4044. Those assumptions are updated quarterly.

assumptions in effect for May 2011, these interest assumptions are unchanged.

PBGC has determined that notice and public comment on this amendment are impracticable and contrary to the public interest. This finding is based on the need to determine and issue new interest assumptions promptly so that the assumptions can reflect current market conditions as accurately as possible.

Because of the need to provide immediate guidance for the payment of benefits under plans with valuation dates during June 2011, PBGC finds that good cause exists for making the assumptions set forth in this

amendment effective less than 30 days after publication.

PBGC has determined that this action is not a "significant regulatory action" under the criteria set forth in Executive Order 12866.

Because no general notice of proposed rulemaking is required for this amendment, the Regulatory Flexibility Act of 1980 does not apply. See 5 U.S.C. 601(2).

#### List of Subjects in 29 CFR Part 4022

Employee benefit plans, Pension insurance, Pensions, Reporting and recordkeeping requirements.

In consideration of the foregoing, 29 CFR part 4022 is amended as follows:

#### PART 4022—BENEFITS PAYABLE IN TERMINATED SINGLE-EMPLOYER PLANS

- 1. The authority citation for part 4022 continues to read as follows:

**Authority:** 29 U.S.C. 1302, 1322, 1322b, 1341(c)(3)(D), and 1344.

- 2. In appendix B to part 4022, Rate Set 212, as set forth below, is added to the table.

#### Appendix B to Part 4022—Lump Sum Interest Rates for PBGC Payments

\* \* \* \* \*

Rate set	For plans with a valuation date		Immediate annuity rate (percent)	Deferred annuities (percent)				
	On or after	Before		$i_1$	$i_2$	$i_3$	$n_1$	$n_2$
* 212	* 6–1–11	* 7–1–11	* 2.50	* 4.00	* 4.00	* 4.00	* 7	* 8

- 3. In appendix C to part 4022, Rate Set 212, as set forth below, is added to the table.

#### Appendix C to Part 4022—Lump Sum Interest Rates for Private-Sector Payments

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Rate set	For plans with a valuation date		Immediate annuity rate (percent)	Deferred annuities (percent)				
	On or after	Before		$i_1$	$i_2$	$i_3$	$n_1$	$n_2$
* 212	* 6–1–11	* 7–1–11	* 2.50	* 4.00	* 4.00	* 4.00	* 7	* 8

Issued in Washington, DC, on this 10th day of May 2011.

**Laricke Blanchard,**

*Deputy Director for Policy, Pension Benefit Guaranty Corporation.*

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## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 100

[USCG–2011–0046; 1625–AA08]

#### Special Local Regulations for Marine Events; Severn River, Spa Creek and Annapolis Harbor, Annapolis, MD

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing special local regulations

during the swim segment of the "TriRock Annapolis" triathlon, a marine event to be held on the waters of Spa Creek and Annapolis Harbor on May 14, 2011. These special local regulations are necessary to provide for the safety of life on navigable waters during the event. This action is intended to temporarily restrict vessel traffic in a portion of Spa Creek and Annapolis Harbor during the event.

**DATES:** This rule is effective from 6 a.m. until 9 a.m. on May 14, 2011.

**ADDRESSES:** Comments and material received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of docket USCG–2011–0046 and are available online by going to <http://www.regulations.gov>, inserting USCG–2011–0046 in the "Keyword" box, and then clicking "Search." This material is also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation,

West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this temporary rule, call or e-mail Mr. Ronald Houck, U.S. Coast Guard Sector Baltimore, MD; telephone 410–576–2674, e-mail [Ronald.L.Houck@uscg.mil](mailto:Ronald.L.Houck@uscg.mil). If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

#### SUPPLEMENTARY INFORMATION:

##### Regulatory Information

On February 17, 2011, we published a notice of proposed rulemaking (NPRM) entitled "Special Local Regulations for Marine Events; Severn River, Spa Creek and Annapolis Harbor, Annapolis, MD" in the **Federal Register** (76 FR 33). We received no comments